2020-2021

SOLLERS COLLEGE

STUDENT CATALOG

Sollers College

55 Parsonage Road, Unit 1850
Edison, NJ 08837

Phone: 848-299-5900
Fax: 732-709-1552

E-mail: admissions@sollers.edu
Website: www.sollers.edu

Mailing Address: 483 Menlo Park
Edison, NJ 08837

Emergency Numbers

Fire Department: 911 or 732-248-7500

Police Department: 911 or 732-248-7400

President's Message

The word **Sollers** is derived from Latin, and means skilled, skillful, clever, dexterous, adroit, expert. That is what we want you to become: **an expert in your chosen field**. We encourage US businesses to create jobs in this country. Instead of outsourcing jobs to India and China, we want to create the skills and the Jobs of the Future, here, *in the USA*.

At Sollers, we believe that ***education is a human right***. All humans should have the opportunity to develop and use their talents to achieve the American Dream. Granted, for many, that dream seems harder than ever to achieve now.

It does not have to be that way. Sollers College has a singular focus: ***to reskill America for the Jobs of the Future.***

In other words, **our job is to help you get a job**. Not just any job, but a Job of the Future, in a field that offers promise and lasting career-building opportunities. Jobs with titles such as data scientist, data engineer, clinical research scientist, research nurse, biostatistician, and many more.

Towards that end, Sollers College's *ikigai (Japanese concept of meaning for being)* is to prepare America for the Jobs of the Future.

Siba P. Padhi

President

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PROGRAMS

INTRODUCTION

Sollers College was founded on May 3, 2016, as an off shoot of the private career school, Sollers, now Clinical Research Academy of America (CRAA). CRAA began as a content development organization in 2007 and evolved into an educational institution that trained adults with Bachelor's, Master's, Ph.D.s, and other advanced degrees to transition into the clinical research industry. The private career school has trained over 1,500 students who currently hold leadership positions in pharmaceutical organizations such as Astra Zeneca, Bristol-Myers Squibb, Covance, Johnson & Johnson, Novartis, and Pfizer.

The College offers Associate to Bachelor's programs, Master's programs, and certificate programs in both Life Sciences and Decision Sciences, and aspires to graduate students who are held to standards that are commensurate to the degrees and certificates they pursue, and the sophisticated skill sets they need for career development.

Description of Facilities

Sollers College is located in a 24,826 square foot facility at 55 Parsonage Road, Unit 1850, in Edison, New Jersey. The school is on the first floor of the Menlo Park Mall. Menlo Park Mall is a 2-level super regional mall that boasts a wide range of retailers including Macy's, Nordstrom, Barnes & Noble Booksellers, Rainforest Café, AMC Dine-In Theatre, Swarovski, and a food court with a wide variety of eateries. Edison is about an hour's drive from New York City.

The facility is adequate to serve the needs of the institution's educational programs, support services, and mission-related activities. The Mall has a convenient and well-lit ample parking space, and high-speed internet access. The Mall's management is on-site, and is responsible for some maintenance services. The building is handicap accessible. The classrooms are spacious and have projectors and Spark Boards to display lecture presentations.

License and Affiliations

Sollers College is licensed by the New Jersey Office of the Secretary of Higher Education (OSHE).

Academic Partnerships: SAS, Tableau, Techsol, MasterControl, and Bio-optronics.

Mission Statement

Our mission is to help individuals gain the knowledge and skills needed for employment and career advancement.

Core Values

At Sollers College our core values do not just instruct us, they inspire us to act with purpose to ACHIEVE our mission and exceed our expectations.

- **Accountability**: We embrace and foster the tradition of holding ourselves accountable for our actions.
- **Community**: We strive to be an integral part of our communities by providing access to education and improving the community where we live and work.
- **Honesty**: We take great pride in dealing with our stakeholders in an open, honest, and ethical manner.
- **Innovation**: We encourage a culture of innovation, as we constantly adapt ourselves to the new, the unknown, and the best.
- **Equity:** We embrace diversity and treat each person with equality, respect, and dignity.
- **Visionary Leadership**: Our leaders work with dynamism and insight to create an environment that nurtures our organizational vision, mission, and core values.
- **Excellence**: Excellence is the result of talented people giving their best and creating an environment where others can do their best as well.

Special Needs

Sollers College is committed to meeting the special needs of individuals with disabilities. In compliance with Section 504 of the Rehabilitation Act of 1973 and the Americans with Disabilities Act of 1990 (ADA), Sollers College does not discriminate against students or employees with disabilities. The institution makes every effort to arrange services for any student or employee who, through a recent (3 years or less) assessment or diagnosis, can document the disability. The student is responsible for all the assessment costs.

Definition of Disability: According to the ADA, a person with a disability is one who exhibits the following: (1) has a physical or mental impairment that substantially limits a major life activity,* (2) has a record or history of such impairment, or (3) is regarded as having such an impairment. (*Major life activities include, but are not limited to walking, seeing, hearing, speaking, breathing, learning, working, caring for oneself, and performing manual tasks. These impairments may exist

in those with chronic health impairments, learning disabilities, emotional disturbances, physical disabilities, etc.).

Disclaimer

Sollers College does not guarantee jobs for students.

Sollers College provides students with excellent academic training to help them compete in the marketplace. We also provide extensive placement services to help students with their job search; it is the student's responsibility to clear the recruitment processes of employers, including interviews.

ACADEMIC CALENDAR
Certificate Programs
January 2020 - December 2020

New Year's Day – CLOSED	Jan 1
MLK Day - CLOSED	Jan 20
February Enrollment Ends	Feb 7
Presidents' Day - CLOSED	Feb 17
March Enrollment Ends	Mar 20
Good Friday - CLOSED	Apr 10
April Enrollment Ends	Apr 24
May Enrollment Ends	May 22
Memorial Day – CLOSED	May 25
June Enrollment Ends	June 26
Independence Day – CLOSED	July 4
July Enrollment Ends	July 22
August Enrollment Ends	Aug 21
Labor Day - CLOSED	Sept 7
September Enrollment Ends	Sept 23
Columbus Day - CLOSED	Oct 12
October Enrollment Ends	Oct 28
Thanksgiving Day – CLOSED	Nov 26
November Enrollment Ends	Nov 25
December Enrollment Ends	Dec 23
Christmas Day - CLOSED	Dec 25
New Year's Eve - CLOSED	Dec 31

ACADEMIC CALENDAR 2020/2021
Degree Programs

Fall Semester

Classes Begin	August 26
Labor Day, College Holiday	September 7
Thanksgiving Holiday	November 26-27
Classes resume	November 30
Last day of classes	December 11
Reading day, final exams begin at 6:00 p.m.	December 16
Final exams end	December 21

Spring Semester

Classes Begin	January 21
Spring recess	March 22-26
Classes resume	March 29
Last day of classes	May 7
Reading days	May 10 & 11
Final exams begin	May 12
Final exams end	May 17
Senior Day	May 18
Commencement	May 22

Summer Session May 27 – August 12

Holidays - 2021

The following holidays will be observed by the school for students and classes will not be held.

New Year's Day	Jan 1
Martin Luther King Day	Jan 18
Presidents' Day	Feb 15
Good Friday	April 2
Memorial Day	May 31
Independence Day	July 4
Labor Day	Sept 6
Columbus Day	Oct 11
Thanksgiving Day	Nov 25-26
Christmas Day	Dec 25
New Year's Eve	Dec 31

Class Schedules/Business Hours

The Student Services Manager provides the class schedule during the first day of orientation. Class schedules are also updated on the Learning Management System. For the latest information on program schedules, students can contact Admissions at admissions@sollers.edu or Student Services at studentservices@sollers.edu or 848-221-1992. Each program varies in clock hours, credit hours, and curriculum.

Our business hours are from 8:30 a.m. to 5.30 p.m. Monday through Friday, and Saturday from 9:00 a.m. to 5:00 p.m. On weekdays, classes are held until 9.30 p.m.

ADMISSIONS

Nondiscrimination Policy

Sollers is committed to providing equal opportunity and access to its occupational educational programs and activities. The school does not discriminate on the basis of race, color, gender,

national or ethnic origin, handicap or disability, age, marital, or veteran status in any of its policies, procedures, or practices.

In addition, recognizing that women and men are equal partners, the school strongly discourages the use of discriminatory language. The school also prohibits any form of sexual harassment by its employees and students.

Admissions Requirements

To be granted admission to Sollers College, a prospective student must complete an application for admission, and subsequently interview with our Admissions Coordinator. In addition, all other general and specific admission requirements must be met, including those regarding age and prior education.

Students in degree programs must request transcripts from the school where they received their Associate degrees (Bachelor's program students) or undergraduate degrees (Master's program students). The minimum GPA for acceptance into either degree program is 3.0.

Age

Each applicant must be at least eighteen years old on the first day of class.

Educational Qualification

Evidence of intellectual achievement, motivation, and aptitude are required for admission to all our programs. At a minimum, a prospective student must have a High School diploma or a GED for some certificate programs. However, an Associate or Bachelor's degree (or higher) in science, healthcare, information technology, computer sciences, or allied domains is preferred.

Students seeking admission into our Bachelor's programs must have an Associate degree, and those seeking admission into our Master's programs must have a Bachelor's degree.

Language Requirement

Our medium of instruction is English, so applicants must understand the English language in order for them to read, write, and interpret complex study material.

Documents Required For Admission

- **Application**: Prospective students can download an application form from our website at http://www.sollers.edu. Students can also speak to an admissions representative by calling (848) 299-5900.

- **Identification:** All prospective students must have a government-issued photo identification.

- **Transcripts:** An official transcript from an educational institution with a minimum GPA of 3.0 is required for degree program admission.

- **Resume:** Submission of a current resume is requested for all programs.

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Program Study Requirement

Computer system: It is mandatory for all students to have lap tops.

Program Transfer Policy

Policy on transfer of students from another institution and transfer of credits from other institutions

Sollers College is committed to helping students reach their educational goals as quickly as possible. However, the certificate programs offered at Sollers are short and measured in clock hours only. Therefore, credits earned at another institution are not applicable, and we do not accept transfer of students from other institutions for **certificate programs**.

We accept transfer of students (and credits) from other educational institutions for our **degree programs.**

Policy on transfer of students between programs within the institution

The modules covered in each of the ***certificate*** programs at Sollers College are different from each other. Therefore, work completed in one program cannot be used toward another program. A student can enroll in more than one program simultaneously, however, he or she has to complete each of the programs separately.

For our **degree** programs, students who successfully earn a Bachelor's degree can apply for admission into our Master's degree programs.

Attendance

A student must agree to maintain regular attendance and to abide by the rules and regulations of the school. Students are expected to maintain at least 80 percent attendance. Violation of school rules and regulations may result in a student's suspension or dismissal. Please refer to the Attendance Policy below for further details.

Making Up For Missed Classes

Certificate program students who miss a class must obtain permission from the Student Services Department to make up for the missed class. This permission must be requested at the earliest possible time (and before the absence, if possible). Students will be given a chance to make up for the missed classes by attending a future session. If that is not possible then the student is required to finish the missed program material on his or her own and post any questions or clarifications he or she needs on the portal for the instructor or faculty member or Student Services Coordinator to address. Please refer to the Attendance Policy below for more details on making up for missed classes.

Students enrolled in degree programs should communicate with the professors and teaching assistants regarding the best way to make up for missing a lecture.

Financial Assistance

Sollers College is committed to helping our students pursue their academic goals. We assist our students in various ways to help them plan and meet expenses associated with attending programs at our school. Apart from regular financing options, Sollers offers a competitive Income Sharing Agreement (ISA) where students can defer from paying for their tuition and other expenses until they gain employment over and above a certain annual base salary ($50,000 gross). The payouts thereafter are at a predetermined amount in accordance with the guidelines of the third-party financial institution handling the ISA.

Scholarships

At Sollers College, we not only recognize excellence, we help our students pursue their career prospects by offering both merit- and need-based scholarships. In order to apply for financial aid, students must file for financial aid. Unfortunately, we do not have sufficient funds to help every student who qualifies for need-based assistance. Priority is given to applicants with the strongest professional backgrounds. The criteria for these scholarships are as follows:

Need based: This scholarship is awarded each year to students who demonstrate financial need and marketable professional skills. The award will help to meet the program fee requirements of qualified students. There is no application to be considered for this scholarship. Applicants are automatically considered through their admission application materials.

Merit based: Criteria is determined by the competitiveness of the applicant pool each year; so there is no set of credentials that guarantees an award.

The Admissions Coordinator has the authority to approve a full scholarship for up to two students per class. In the event of special circumstances, the Admissions Coordinator may approve full scholarships for more students in each class.

Students who are unemployed or are earning less than $50,000 yearly may be given special consideration for financial help from the school. Approval from the Admissions Coordinator is necessary.

External Grants - Certificate Programs

The certificate programs that are offered by the College and listed on the ETPL are approved by The Center for Occupational Employment Information (COEI), New Jersey Department of Labor and Workforce Development (NJ DOL&WD). Students attending our programs are eligible for NJ DOL&WD grants provided they meet all the eligibility requirements outlined by the county they reside in (or choose to apply from).

To check for your eligibility, please follow the steps below:

1. Go to the New Jersey Training Opportunities website http://www.njtrainingsystems.org/.
2. On the homepage, click on One Stop Career Center.
3. Once on the One Stop Career Center page, on the right hand side of the page, you will see 'Find your Location' tab. Click on the county that is applicable and it will bring you to a page that contains the contact information of the local one-stop career center.
4. Call the local one-stop career center and make an appointment with the counselor.
5. The counselor will provide the paperwork and all other information about the training program.
6. Approval of the training grant will only be at the discretion of NJ DOL&WD.

Payment

Payment Method

We accept cash, credit, and checks as forms of payments. Please make checks payable to Sollers. Initial payment must be received before the program starts and all fees must be received by the

school before the program ends. Students receiving funding through the Department of Labor and Workforce Development must have their contracts approved before the start of the training program.

Payment Schedule

Total fees due for a program must be received before the program starts. However, we do offer flexible payment options. These options are discussed during the first interview with the Admissions team.

If a student withdraws from the program and is on an installment plan, the difference between what is owed and what has been paid will be settled between the student and the school according to the school's refund policy as outlined below.

Payment Enforcement

Students who do not make payments for more than a month and have no payment arrangement with the Accounts Department will be dropped from the program and necessary administrative action will be pursued. Certificates and diplomas will not be granted to those who do not make their payments.

Cancellation and Tuition Refund Policy (Self- Pay Students ONLY)

The school may retain the registration fee plus a pro-rata portion of the tuition calculated on a weekly basis. The Student Services Coordinator and the Admissions Coordinator must be notified in writing within 5 business days of the date of withdrawal. The school shall adhere to the following refund policy in the event of notification by the student of withdrawal from the school or termination by the school prior to completion of the program.

Time of Withdrawal	Student's Responsibility
Within 3 business days of signing the contract	0% of total tuition plus registration fee
During the first week	10% of total tuition plus the registration fee
Weeks 2 and 3	20% of total tuition plus the registration fee
After 3 weeks & prior to 25%	45% of total tuition plus the registration fee
After 25% of program and before 50%	70% of total tuition plus the registration fee
After 50% of program is completed	100% of total tuition plus registration fee

- Students must complete a Withdrawal Form, which is available at our Student Services Department.
- Refunds, when due, will be made automatically within 45 days of receipt of the Withdrawal Form signed and dated by the student.
- If a student never attended any class, or cancels the contract prior to the class start date, any payment received by the school will be refunded within 45 days. All approved refunds are subject to a 5 percent service fee (up to $100). There will be no refund without the original receipt and no CASH refunds will be made.
- Students who are or remain in absentia for the classes without prior intimation to the school or who have voluntarily dropped out without informing the school will be charged tuition for the classes as per the refund policy mentioned above.
- If the program is cancelled by the school for any reason, a full refund will be made within 45 calendar days from the date of cancellation.

Income Share Agreement Structure and Refund Policy

An Income Share Agreement (ISA) is a legal contract between a student and the school. The ISA contract outlines that in exchange for the provision of an education to a student, the student agrees to pay a fixed percentage of their income for a fixed duration of time. Payment occurs when the student is employed and earning above a predetermined minimum salary. ISA contracts have Payment Caps that clearly indicate the most a student would pay given the terms of their ISA contract. An ISA contract has the following terms:

- Instead of paying tuition upfront, enrolled students may choose to sign an Income Share Agreement.
- An ISA is a legally binding agreement representing a responsibility to pay XYZ a portion of future income.
- Income Share Agreements are not a form of debt, nor are they a loan. They have no interest rate or principal balance.
- Students who elect the ISA option agree to pay (Income Share %) % of post-XYZ gross income (i.e., before taxes) with (Payment Term) monthly payments, but only when students are earning equal to or more than (Minimum Income) per year.
- The ISA option is capped at a maximum of (Payment Cap).
- Students have (X) years after their last day at XYZ to complete the (Payment Term) monthly payments. After that period, the ISA is cancelled.
- If a student gets a job before graduation, they are not considered withdrawn and their ISA will be due in full.

Withdrawal and Refund Policy: Students can withdraw from an ISA within three business days

of attending class.

STUDENT SERVICES

The Student Services Manager provides and maintains all student-related essential processes. The department assists students with all activities related to class registration, any changes to class schedules, calendar, name and address changes, as well as graduation information. Student Services personnel prepare classrooms and print out program materials before each class. They also answer any inquiries, with confidentiality and integrity for our students and faculty, while supporting Sollers College's overall mission.

Students cannot attend or receive credit for a program unless they are properly registered for a program and have met their financial obligations to the school.

Student Records

Student records will be maintained by the College for as long as the College exits. If the College closes down for any reason, the College will make arrangements with the Office of the Secretary of Higher Education (OSHE) to store records for students in our Bachelor's and Master's degree programs; students earning certificates from the school may obtain their records from the New Jersey Department of Labor and Workforce Development.

We are committed to maintaining the confidentiality of student records in line with the Family Educational Rights and Privacy Act (FERPA). Employees of the school will not release the address or telephone number of any student to persons not authorized by the student to receive information.

The Student Services Department is responsible for maintaining student files. The school maintains the following records for each student:

- Application forms
- Academic transcripts, photo identification, and resume (Transcripts for Certificate students are issued upon request)
- Attendance record
- Graduation certificates and diplomas
- Accident and health reports, if any.

Media Services

Media Services supports academic functions, provides equipment to support classrooms and virtual classrooms (online) fully, and also provides training and consultation to support all our students in their media needs.

Academic Support

Media Services provides support for classes and other academic functions. All the classrooms are equipped with Spark Boards, built-in projectors, computers or laptop hookups, and video players. In spaces without installations, Media Services will set up the required equipment.

Computer Labs

We have a dedicated student lounge for students to practice and complete their homework and quizzes. The Computer Lab mainly has desktop computers.

Consultation, Training, and Other Media Needs

Apart from in-class hands-on training, we also schedule hands-on training sessions for individuals or groups with our faculty members using Microsoft Teams. We video-record the session for later reference or for students who miss their class for a valid reason.

Learning Management System (Learning Portal)

A Learning Management System (LMS) is the software application for the administration, documentation, tracking, reporting, and delivery of learning education courses or training programs. Our LMS is accessible from any computer with internet access, and is available to students at all times. Our program material is also available for studying on the Learning Management System portal. Access to the portal is also given upon enrollment in the Student Welcome Package given to all students by the Student Services Department.

Some typical features of our portal are:

- Assignment submission
- Files download
- Grading
- Calendar
- Quiz
- Final assessment.

Library Services

Academic libraries are an integral part of a school's academics and learning culture, and Sollers College is no exception. The 21st Century academic library is a hub for a specialty center that informs the school's brand and helps attract and retain students.

The school's library is housed in the student lounge, which is also the study area and computer lab in order to create an environment where students learn in a collaborative manner, fellowship, and engage in healthy debate rather than studying solely in isolation. Working and learning in isolation is no longer an option because today's students learn by accessing knowledge and exploring new ideas among their peers.

To ensure that students are equipped with the skills they need to conduct research successfully during their studies at the school and in their professional work, Sollers College has developed an Information Literacy Plan that is aligned with the Association of College and Research Libraries's (ACRL) *Information Literacy Competency Standards for Higher Education*.

Students will develop information literacy skills through research-intensive assignments including a capstone requirement. The information literacy program will teach students to find, evaluate, analyze, and synthesize information in their fields of study. Students will become familiar with the key resources used by professionals in their respective disciplines.

Study Lounge
Students have access to desktop computers that access the internet and learning portal.

Counseling

Academic and Career Counseling
We help students determine the best fit to our programs based on the student's background, professional goals, and skills. It is a discovery process and often gives valuable insight into how to maximize strengths and position weaknesses.

Career Planning and Guidance
After assessing gaps a student possesses for a particular career, our advisers will work with the student to help develop the skills needed to succeed in today's competitive job market.

Resume Review and Critique
Our experts in the area can provide valuable critique to help improve a resume, so that it gets picked up by recruiters. We review everything from formatting, grammar, key messaging, layout as well as any other improvements that can be made.

Placement Services

At Sollers College, we assist our students with their job search. While employment cannot be guaranteed, we place great emphasis on assisting our graduates in starting meaningful careers. It is our goal to connect eligible students with our pool of recruiters and networking partners. We actively market our students' resumes for maximum exposure and for a possible short listing for a job.

We have developed our occupational programs based on professional standards. From the very beginning, the program delivers what is needed to succeed in each field. Our curriculum offers the knowledge necessary to enter the industry. Our certificates and diplomas serve as proof that our students are prepared to handle careers in clinical research, drug safety and related areas, and decision science. Furthermore, our participation in career fairs and job postings on our blog and website helps us get in touch with local employers. Our Placement Services Team compiles a list regularly.

In addition to one-on-one service, we strongly encourage the use of career websites and national organizations to enhance job searches. These suggestions enable students to look for opportunities on a local, state, and even national level. The websites give students the resources necessary for jobs, internships, resume writing tips, networking strategies, and guidance for interviews.

POLICIES AND PROCEDURES

At Sollers College, we strive to provide a safe and secure facility for our students, faculty, staff, and visitors. To promote the health, safety, and security of everyone who uses our facility, policies and procedures are in place. Our safety policy prohibits violence, drugs and alcohol, as well as possession or storage of firearms or other weapons at our facility.

Fire Evacuation

In the event of a fire in the College building or the Menlo Park Mall proceed as follows:

- If you detect signs of a fire such as a burning odor or smoke, evacuate the building immediately and call 9-1-1.
- If the fire alarm has not activated, activate an alarm pull station as you exit. Call 9-1-1 and report your observations.

- Remain calm and cooperate with emergency responders from the College, Menlo Park Mall, Edison Fire Department.
- If conditions permit, close doors as you leave to help contain the fire and smoke.
- Crawl low under the smoke where the air is cleanest if you have to exit through an area that is filling with smoke.
- If you are in the lunch room, the conference room, any of the classrooms, or the College premises, feel the door with the back of your hand. If the door is warm, try to find an alternate way out of your location. If the door is cool, open it slightly and check for smoke. If the premises are not engulfed in smoke use the nearest and safest fire exit to evacuate.
- Once you have exited the building do not re-enter the building. You can only enter the building after the Fire Department gives a signal that it is okay to do so.
- After exiting the building, go to the parking lot outside the Mall or the designated assembly area assigned by the emergency responders. Report any unaccounted for persons to the emergency responders.
- In case you are unable to evacuate from any of the classrooms, conference room, or the College premises, seal the doors with wet towels or clothes, or with duct tape. Notify 9-1-1 of your location and situation. Protect your hands, face, nose, and mouth with wet cloths and dampen your clothes.
- If your clothes catch fire, stop, drop to the floor or ground, and roll; cover your face with your hands.
- If you are in another section of the Mall instead of the College premises, use stairs to evacuate not an elevator.

Severe Weather

Snow, Ice, Severe Winter Weather

Driving, walking, and any outdoor activities can be dangerous during any severe winter weather such as blizzards, heavy snow, and ice storms all of which can decrease visibility, lower temperatures to a dangerous level, bring about high winds, and icy roads and sidewalks.

- In the event of a school closing, the Director of Emergency Operations will ensure that all employees receive a text message or voicemail, and that the College website announces the school closing so that students are aware.
- Avoid unnecessary travel or outdoor activities, but if you must be outside, wear several layers of warm clothing, gloves, boots, a hat, scarf or face mask to stay warm and prevent frostbite.
- Have a "GO KIT" in your car that contains essential emergency items such as blankets, food, water, flashlight and extra batteries, cell phone, in case you get stranded on the road.

- Drink plenty of nonalcoholic fluids and eat foods that are high in calories to help maintain body heat.
- If you are trapped on the road in a blizzard, turn the hazard lights on and remain in your vehicle. Run the engine and heater for about 10 minutes every hour to help stay warm and open the window slightly for ventilation; clear the snow from the exhaust pipe periodically. Drink fluids to avoid dehydration, even if you are not thirsty.
- If the weather keeps you at home, allow continuous drips of water to flow from your faucets to prevent your pipes from freezing.

Hurricane

In the event of a hurricane, New Jersey State of Emergency announcements will take precedence. The Director of Emergency Operations will ensure that all employees receive a text message or voicemail regarding school closure, and that the College website announces the school closing as well.

- Be prepared to evacuate, especially if you live along the coast or in an area that is prone to flooding.
- If you are sheltering in place during a hurricane, take refuge on the ground floor in a windowless central room, closet, or hallway. Get under a table or some other strong object and stay away from glass doors or windows. Brace all outside doors, and close all inside doors.
- After the hurricane passes, monitor the media for official information and instructions. Turn off the utilities in your home, if you did not do so prior to the storm, and inspect your home for utility damage caused by the storm.
- Until the authorities declare the drinking water safe, do not drink tap water; and do not drive unless it is essential.

Lightning/Windstorm

Do not leave the building in the event of a severe thunderstorm with lightning. Stay away from windows, outside doors, plug-in electrical appliances, and metal fixtures. Do not use your telephones. If you happen to be in a vehicle in the parking lot, stay in the vehicle. Avoid walking in puddles when you leave the building or vehicle.

If a tornado is spotted in the area, all students and employees should stay put on the College campus unit, especially since there are no windows. Assume the "duck and cover" position by kneeling on the floor with your head tucked in front of your knees and your arms over your head.

Heat wave

Long periods of excessive heat can be dangerous and can lead to death. Slow down and avoid strenuous activity. Stay indoors as much as possible, especially in an air conditioned environment. Drink plenty of water, and avoid alcohol and caffeine to avoid dehydration. Wear lightweight and light colored clothing since light colors will reflect away some of the hot energy from the sun.

Do not leave children or pets in the car even with the windows down. When the weather is 83 degrees F outside and your car windows are at least 2 inches down, the temperature in your car can reach 109 degrees F in about 15 minutes.

If you or anyone experiences vomiting, cramping, or loses consciousness because of the heat do not eat or drink, or do not feed the person or allow the person to drink. Call 9-1-1 and alert a medical professional as soon as possible.

Pandemic

Infectious diseases that have the potential to spread locally and globally pose a unique challenge. The Emergency Management Team will activate the Emergency Operations Plan (EOP) to an appropriate level to provide support for the health threat response or health emergency. The Team will monitor information sources identifying domestic and international health threats to determine if or when actions may be useful or necessary to protect members of the College community at home and abroad.

The objective in the event of a pandemic is to reduce the potential of spreading infection. The necessity for issuing notice of a disease infecting all or part of the campus community will be determined by the appropriate medical authority, principally, the New Jersey Department of Health, the Center for Disease Control, and the World Health Organization.

The Emergency Management Team will make every effort to educate the College community by covering topics such as the following:

- Description of symptoms
- What the risks associated with contracting the disease are
- If, when, and where vaccinations will be available
- If and how the disease may be carried by people who are infected by the disease
- Alleviation of fear of contracting the disease or receiving vaccination

- Announcements regarding if, when, and where any public meetings about the disease may be available.

Communication regarding mitigation actions may include the following:

- Hand washing and cough hygiene
- Staying away from the campus when ill
- Not sharing drinks and cigarettes
- Voluntary isolation.

Sollers College administration may take more protective measures to actively reduce the spread of disease, including but not limited to the following:

- Cancelation of classes for a period
- Interventions that include iterative symptom monitoring and quarantine
- Travel restrictions to affected areas
- Enhanced environmental hygiene
- Immunization and other preventive measures recommended by health authorities.

Attendance Policy

To attend a program, students must abide by the following guidelines:

- Students must be properly registered and must pay the fee in accordance with the payment schedules for the program.
- Students are expected to attend all lectures, take all their module quizzes and the final exam or assessment based on the program requirements.
- In case you are late for a class or have to leave before the class is over, it is preferred that a prior notification be given to the instructor.
- Students who miss a class must obtain permission from the program instructor and student services to make up for the missed work. This permission must be requested at the earliest possible time (and before the absence, if possible). It is the student's responsibility to inform the Student Services Department.
- Students will be given a chance to make up for the missed classes by attending a future session. If attending a future session is not possible, then students can request the program material from the instructor and will be required to complete it on their own. Such requests must be routed through the Student Services Department.

- If they wish to finish the program they will have to sign a new contract in the next available enrollment period. In they choose not to re-enroll then they will be responsible for paying for the classes taken thus far in addition to the nonrefundable $100 administrative fee.
- Three tardy appearances or early departures, will count as one absence.
- If a student is absent for 3 weeks or more in a row without a confirmed valid reason (which has been approved by the Student Services Department), they will be dropped from the program, and will need to re-enroll in the next admissions period, and pay the required readmission fees, in order to complete training.

Leave of Absence/Withdrawal

- Students who interrupt their class schedule should formally notify the school.
- All students requesting a leave of absence must complete a Leave of Absence Form.
- All students who are withdrawing must complete a Withdrawal Form. Simply notifying the instructor or no longer attending classes does not complete the process.
- Leave of Absence and Withdrawal Forms are available from the Student Services Department.
- Not completing the Leave of Absence Form will result in tuition being charged to midpoint of the semester from the last date the student attended any academically related activity even an exam.
- Students are required to fill out all information required on the forms. Completed forms must be submitted to the Student Services Department for the President's signature. The process of taking a leave or withdrawing will not be complete until all necessary signatures are on the form.

Note: Each individual situation will be handled privately. In case of a leave, the school will make every effort to help students meet their educational goals. It will be necessary to meet with the Student Services Manager before returning to class.

Code of Conduct

Sollers College has a No Tolerance policy for the following, and official action will be taken by the President that could result in termination, if found guilty:

- All forms of bias including race, ethnicity, gender, disability, national origin, and creed as demonstrated through verbal or written communication or physical acts.
- Sexual harassment including creating a hostile environment and coercing an individual to perform sexual favors in return for something.

- All types of bullying, proven dishonesty, cheating, plagiarism, knowingly furnishing false information to the institution, and forgery including alteration or use of documents of identification with intent to defraud.
- Intentional disruption or obstruction of teaching, research, administration, disciplinary proceedings, public meetings and programs, or other school activities.
- Physical or mental abuse of any person on school premises or at functions sponsored or supervised by the school.
- Theft or damage to the school premises or damage to the property of a member of the school community on the school premises.
- Failure to comply with school policy and procedures and follow the directions of school officials acting in their official capacity.
- Dress code - each student is expected to maintain a business casual and professional appearance.
- Violation of the law on school premises in a way that affects the school community's pursuit of its proper educational objectives. This includes, but is not limited to, the use of alcoholic beverages or controlled dangerous substances, drugs, and firearms on school premises.

Conditions For Dismissal

A student may be dismissed from the school for the following reasons:

- Not adhering to the school's rules, regulations, policies, and code of conduct
- Carrying controlled drugs, alcohol, knives, and firearms
- The President will notify the student in writing should it become necessary to dismiss the student. The dismissal letter will contain the date and the reason for the dismissal. It is the responsibility of the dismissed student to notify the institution or county of his or her dismissal from the school, if he or she received a grant from the county to take a program at Sollers College. Prepaid tuition will be refunded according to the school's refund policy.

Copyright Infringement

All copyrighted materials must be used in conformance with applicable copyright and other laws. Downloading or distributing copyrighted material, for example, documents, books, programs, videos, text, and so on, without permission from the rightful owner, violates the United States

Copyright Act. Further, the copying of digital copyrighted materials, such as third-party software, without the express written permission of the owner of the proper license is illegal.

Students are prohibited from using file-sharing networks on any school-provided network, including the Wi-Fi network. You can report alleged copyright infringements on Sollers College systems or direct other copyright questions to info@sollers.edu.

Grievance Policy and Procedure

Sollers College desires to resolve student grievances, complaints, and concerns in an expeditious, fair, and amicable manner. A student with a grievance may initiate the resolution process.

- The student is advised to discuss the grievance informally with the person who is the source of the grievance. If the grievance is resolved at this level then the matter is considered closed.
- If the grievance is not resolved at this level, the student may request a formal review by the Student Services Department.

    1. If the source of the complaint is another student, the Student Services Manager will speak to the student to resolve the matter.
    2. If the complaint is not resolved at the level of the Student Services Manager, it is taken to the Student Services Director.
    3. If the source of the complaint is a school employee, then the Human Resources team or the President will resolve the matter.

- The student is required to fill out a formal complaint by filling out the Student Grievance Form available from the Student Services Department and submitting it to the Student Services Manager. All formal complaints will be addressed and every attempt at resolution will be made by the Student Services Director or the President.
- For students who receive grants from counties, Sollers College will make every attempt to comply with the grievance policy of the county from which the student receives his or her grant.

PROGRAMS

Program Completion Requirements

Financial Requirements

1. Full tuition must be received by the school before the training begins.
2. Final tuition payment, if any, should be received by the school before completing the training.

Sollers College Certificate Requirements

1. You must score 70 percent on the final exam to pass or the final evaluation as per the requirement of the program
2. You must attend 80 percent of the classes of your respective program in person at the school (unless given consent by the President).
3. You must complete all the assignments on the Learning Management System portal based on the program requirement.
4. You must fully meet all your financial obligations to the school.

Grading Policy (Only for Degree Programs)
(Transcript is only upon request for certificate students)

Letter Grade	Percentage	GPA
A+	97%+	4.33/4.00 or 4.00/4.00
A	93%-96%	4.00/4.00
A-	90%-92%	3.67/4.00
B+	87%-89%	3.33/4.00
B	83%-86%	3.00/4.00
B-	80%-82%	2.67/4.00
C+	77%-79%	2.33/4.00
C	73%-76%	2.00/4.00
C-	70%-72%	1.67/4.00

ACADEMIC PROGRAMS DESCRIPTION

The following are the academic programs offered at Sollers College.

Associate to Bachelor's Programs

Associate to Bachelor of Science in Clinical Research

The Associate to Bachelor of Science in Clinical Research program is designed to provide students with a thorough understanding of how the drug development process undergoes experimental evaluation in human beings before the drug gets licensed for marketing. Students will learn about the development of the regulatory compliant activities that are involved in creating documents, and in conducting, recording, monitoring, and reporting clinical trials in human beings.

Students will gain a broad-based understanding of the science, regulatory, and business aspects of developing new therapies to treat illness and improve quality of life. The program is designed to provide students with extensive practical sessions in Oracle Clinical and SAS (Statistical Analysis System) to enable students to gain the rigorous hands-on experience that is required for gainful employment in the pharmaceutical industry. Students will complete a semester-long internship during their final semester that will provide them with hands-on experience and preparation for a career in clinical research.

CIP Code: 51.1005
Total Credits: 60
Program Code: BSCR
Program Mode: Hybrid

Semester 1

BSCR 01 General Basic Subjects **Credits: 9**

BSCR01.1.0 Medical Terminology **Credit:1**

Students will learn how the human body's related medical terminology are created and used for diseases, procedures, treatments as applied to every human body system. This is a fundamental knowledge necessary for any Clinical Research activity.

BSCR01.1.1 Clinical Symptoms, Signs, Diagnostic Procedures Credit:1

After learning medical terminology, the students learn the application of these terminology in relation to drug development and understanding and analysis of Adverse Events that get captured, reported, and analyzed at different stages through application of clinical trial and drug safety data. This includes understanding of What is a Symptom? What is a Sign? What are Diagnostic procedures? What is the importance of reports from these procedures? Learn to corelate all these to various body systems to understand and appreciate the fundamental issues dealt with in clinical research for drug development.

BSCR01.1.2 Basic Computer and IT Literacy Credit:1

Students must be proficient in basic computer functionality to be able to work with Microsoft Office modules, and Sollers College learning portal. This will include the etiquette to participate through the learning portal in eDiscussion Forums, eAssignments, and Remote attendance of learning modules.

BSCR01.2.0 Basic Introduction to Clinical Research Types Credits:5

The student explores the different areas and types of Clinical Research, phases of drug and device development. The module covers basic concepts such as Case Study, Cross sectional, Cohort, and Clinical Trials, with specific advantages, benefits, and limits of these Clinical Research areas.

BSCR01.3.0 Semester 1 Project Credit:1

Students will work to prepare an independent project connecting all the above modules under the guidance of the faculty.

Semester 2

BSCR02 Supportive Areas of Clinical Research Credits: 9

BSCR 02.1.1 Literature Search Credit:1

Literature search is a very important component of information to support any type of Clinical Research work. Here the students will learn how to undertake a literature search of Medical Library Research at PubMed and other publicly available databases in clinical areas.

BSCR 02.1.2 Medical Writing Part 1-2 Credits:2

Medical writing is a very crucial area for specific type of communication that is targeted at a very specific audience and for very special purposes. In the first part, the students will learn the basic fundamental requirements of the American Medical Association, adopted and recommended and approved methods of Medical writing; while in the second part, there will be the application of this writing for different purposes like: Protocol, Investigator Brochure, Informed Consent, Clinical Study Reports, and other Regulatory documents.

BSCR 02.1.3 NIH Grant Submission Process **Credits:2**

The National Institute of Health (NIH) is the biggest funding source for most of the university affiliated hospitals conducting Clinical Research in various therapeutic areas. This module sensitizes the students to learn about the pre-requisites of preparing NIH Grant application procedures.

BSCR 02.2.0 Introduction to Epidemiology **Credit:1**

Students in this module will learn that Epidemiology is the basic science to find out How a disease occurs? How, Why, and Where the disease spreads? Who gets affected and Why? This is followed by an analysis to learn how the spread can be controlled and prevented.

BSCR 02.2.1 Introduction to Biostatistics **Credit:1**

Students in this module will learn how the quality information of Epidemiology gets converted to quantified information that can be analyzed, interpreted to make conclusions, and forecasts about the Prevalence, Incidence, Rates, Ratio-Proportions, and various analysis about risk of the disease and outcome analysis.

BSCR 02.2.2 Introduction to Ethics in Clinical Research **Credit:1**

Students in this module will learn about what ethics in Clinical Research is all about, its evolution, and its relevance to support various regulations to ensure voluntary participation and safety of the subjects in clinical trials.

BSCR 02.3.0 Semester 2 Project **Credit:1**

Students will work to prepare an independent project connecting all the above modules under the guidance of the faculty.

Semester 3

BSCR03 Types of Clinical Trials **Credits: 9**

BSCR 03.1.0 Drug Development Process **Credit:1**

This module will provide an understanding of the entire life cycle of a drug. Students will learn how new molecular entities are discovered; followed by various tests conducted during In-Vitro and Pre-Clinical testing of the drug molecule. Students will also study the creation of the Investigator's Brochure capturing the story of the drug development process and clinical trial development in various stages as Investigational Medicinal Product. Finally, students will discover that the drug gets approval to come to market for specific indications, and with usage guidelines as Active Pharmaceutical Ingredient. The drug will remain in the market as long as its risks can be controlled, and efficacy can allow its safe use.

BSCR 03.1.1 Phases of Clinical Trials, Types of Clinical Research **Credit:1**

Students learn in detail about different phases of clinical trials, risk-benefit assessment, the different stakeholders, protocol, informed consent, clinical oversight, institutional review board, Good Clinical Practice (GCP), investigational clinical supplies, data management activities, safety reporting, and monitoring.

BSCR 03.1.2. Clinical Trial Designs **Credit:1**

This module provides detailed study of the protocol that provides various clinical trial designs for the conduct of clinical trials with different aims and objectives. The details of randomization, blinding, controls, and placebo arms, become intricate parts of the study of various types of trial designs, endpoints, and analytical backgrounds.

BSCR 03.1.3. Advancements and Statistics of Clinical Trial Designs **Credit:1**

This module deals with the latest ICH Guidelines about creating advanced versions of clinical trial designs, and applied statistical methods to evaluate efficacy outlines along with risk-benefit analysis in randomized controlled trials.

BSCR 03.1.4. Cohorts and Post-Marketing Surveillance Trials **Credit :1**

Students learn about the post-marketing surveillance or Phase IV clinical trials through prospective cohort analysis modules applicable to all new drugs that come to the market; as well as for very risky drugs that remain under very special distribution, observation, and analysis under REMS (Risk Evaluation and Mitigation Strategy) programs.

BSCR 03.2.0. Study of Epidemics **Credit:1**

Students will learn the basics of Epidemiology Methods, Importance of Host-Agent-Environment triad; Demographics and Vital Statistics for Population Health, and various established parameters of health outcome study.

BSCR 03.2.1. Role of Protocol for Clinical Study **Credit:1**

Protocol is the most important core document that students will study. They will learn to appreciate how each step of the conduct of clinical trials is provided with scientific considerations of the evaluation of the efficacy of the drug development process, balanced with the safety considerations of the participants. They will also cover the importance of protocol for data analysis, subject safety, and regulatory compliance.

BSCR 03.3.0. Semester 3 Project **Credits:2**

Students will work to prepare an independent project connecting all the above modules under the guidance of the faculty.

Semester 4

BSCR04 Applied Clinical Trial Special Area of Data Analysis **Credits: 9**

BSCR 4.1.0. Clinical Database EDC, eCRF, eClinical Technology **Credits:2**

Students learn about Oracle Clinical Database and its applications for Clinical Data Analysis. Along with a basic understanding of the latest eClinical Technology applications like Electronic Data Capture (EDC), Electronics Case Record Form (eCRF), and various others.

BSCR 4.1.1. Clinical Trial Designs, Endpoints, Sample Size, Randomization **Credit:1**

Students will learn how sample size calculations are implemented as per ICH Guidelines, as part of clinical trial designs, and the role of end points in clinical trials to finalize various methods and types of analysis of data from Oracle Databases.

BSCR 4.2.1. Statistical Methods for Randomized Clinical Trials **Credit:1**

Students will learn why randomized controlled trials are Gold Standards for the ultimate outcome of the clinical trials. This includes very special statistical approach to evaluate Phase I, Phase II, and Phase III trials for submission of study reports to the FDA.

BSCR 4.2.2. Statistical Methods for Post-Market Risk-Benefit Evaluations Credit:1

Students in this module will learn through different exercises how periodic risk-benefit evaluation reports carry the detailed information in statistical tabulated narratives through the ongoing prospective cohort studies after the drug enters the open market.

BSCR 4.2.3.1. Statistical Application Software (SAS) Base and Advanced Credit:1

Students will learn how to work with Base and Advanced Clinical SAS Statistical Application Software (SAS).

BSCR 4.2.3.2. SAS CDISC Compliant Data Analysis Credit:1

In this advanced module of SAS, students will have additional training with examples and exercises of creating statistical tables that are compatible with regulatory needs of ICH and meet CDISC compliance.

BSCR 4.2.4 Healthcare and Clinical Trial Analysis Tools Credit:1

This module provides the opportunity to learn how healthcare data analysis can be performed. This will be through examples and exercises from the published CDC Data sets and its available software for analysis. Students will also learn the concepts and basics of Clinical Trial Management System (CTMS); Electronic Trial Master File (eTMF); and Risk-based Monitoring (RBM) software tools.

BSCR 4.3.0 Semester 4 Project Credit:1

Students will work to prepare an independent project connecting all the above modules under the guidance of the faculty.

Semester 5

BSCR05 Ethics Evolution for Clinical Trials Credits: 9

BSCR 5.1.1 Basics of ICH/GCP and US FDA **Credits:3**

In this module, students will learn the evolution and the need of ethics guidelines for human subjects in clinical research as applicable today through the International Council of Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and its founding influence toward the enactment of rules and regulations by the countries of the world, including the FDA in the United States, and various other applicable local regulations for the conduct of clinical research.

BSCR 5.1.2 Ethics, Institutional Review Boards, Recent Advances in Ethics **Credit :1**

Students in this module will explore the modern technology trends and challenging situations to deal with vulnerable populations, emergency and orphan drug trials, as well as ethics in relation to genetics and biosimilar molecules. Students will also learn how Institutional Review Boards (IRBs) function to ensure that the sites where clinical trials are conducted are in compliance for purposes of protocol, informed consent, investigator's contract, Adverse Event reports, advertisements, compensation, and various ethics issues to the satisfaction of the FDA authorities in the United States.

BSCR 5.2.1. Clinical Trial Startup Activities **Credit:1**

Students learn about ICH/GCP and US FDA Regulations; Roles and Responsibility of various stakeholders and Clinical Trial Monitoring functions through various stages of Clinical Trials.

BSCR 5.2.2. Clinical Trial Initiation and Conduct **Credit:1**

Students learn the process of site initiation and interim monitoring activities through the conduct of the trials, whether Central-Off-site(Remote), or on-site monitoring to ensure thorough GCP compliance to the protocol to attain safety of the subject and integrated scientific data from the trial. This will include understanding various monitoring logs, reports, and integrated communications between all stakeholders. Students will get the initial flavor of eCRF EDC and CTMS for conducting risk- based monitoring activities.

BSCR 5.2.3. Clinical Trial Closeout **Credit:1**

Students continue to learn how a typical Clinical Trial Site comes to the close of the trial activity and the role of the monitor to ensure continued compliance at the site for any FDA audits and inspections in the future. The module will further provide the opportunity to learn how the site close out reports are prepared and all the activities that get covered in the final site close out report.

BSCR 5.3.0 Semester 5 Project **Credits:2**

Students will study the templates of various monitoring functions and reports, budgets and contracts, and prepare an independent project connecting all the above modules under the guidance of the faculty.

Semester 6

BSCR06 Recent Trends in Clinical Trial Technology **Credits: 9**

BSCR 6.1.1 Tools for Conduct of Clinical Trials and Monitoring-Part 1 **Credits:3**

Students learn the basic understanding and creation of IB, Protocol, EDC, IRB, and other essential documents for regulatory compliance of 21 CFR for GCP. This includes eClinical Technology as applicable to clinical trials at different stages, and for different functions like Protocol, Informed Consent, Essential Documents, EDC, and its linkage through Clinical Trial Management Systems.

BSCR 6.1.2 Practical Hands-On Training in Tools - Part 2 **Credits:3**

This is a "Hands-On Learning" module linked with Risk Based Monitoring (RBM) tools and others as that will be contemporary to the technology application.

BSCR 6.2.1 Practical Hands-On Training in Tools **Credits: 2**

Clinical Trial Management System (CTMS), eTMF, ePRO, EDC, eISF, eCTD, tools.

BSCR 6.3.0 Semester 6 Project **Credit:1**

Students will work to prepare an independent project connecting all the above modules under the guidance of the faculty.

Semester 7

BSCR07 Capstone Project-Thesis Project Work **Credits: 6**

BSCR 7.1.0 Clinical SAS **Credits: 3**

Students will perform “Hands-On” learning and undergo training in Clinical SAS application tools for Clinical Data Analysis.

BSCR 7.2.0 Capstone Projects **Credits:3**

In this capstone course, students analyze business, ethical, cultural, and practical aspects of clinical trial conduct; explore trends and technologies driving efficiencies in clinical trial performance; and demonstrate how ethical and regulatory principles and trial management practices align to ensure quality and compliant clinical research conduct.

Associate to Bachelor of Science in Data Engineering

The Associate to Bachelor of Science in Data Engineering program is a highly selective program for students with a strong background in computer science and information systems. Data engineers are the designers, builders, and managers of the information or “big data” infrastructure. They may work closely with data architects (to determine what data management systems are appropriate) and data scientists (to determine which data are needed for analysis). Their ultimate aim is to provide clean, usable data to whomever may require it.

In this program, students will learn key techniques used to design and build big data systems. They will also gain familiarity with data-mining and machine-learning techniques that are the foundations behind successful information search, predictive analysis, smart personalization, and many other technology-based solutions to important problems in business and science.

Building on a core of computer science, information systems, statistics, and mathematics, the curriculum will focus on the foundations of data engineering, big data database management, data mining, machine learning, business analytics, and scientific visualization. Students will work with the biggest tools in the industry including Oracle SQL, Hadoop, MapReduce, Java, Python, and R and RStudio. A capstone experience, in which students will obtain, condition, explore, model, and interpret a big data set, is central to the degree.

CIP Code: 11.0802
Total Credits: 72
Program Code: IDS
Program Mode: Hybrid

SEMESTER 1 SEMESTER TOTAL CREDITS : 16

CODE	TOPIC	CREDITS
IDS301	INTRODUCTION TO COMPUTER SCIENCE & INFORMATION TECHNOLOGY	3
This course provides a foundation for programming and problem solving using computer programming, as well as an introduction to the academic discipline of IT. Topics include variables, expressions, functions, control structures, and pervasive IT themes: IT history, organizational issues, and relationship of IT to other computing disciplines. The course prepares students for advanced concepts and techniques in programming and information technology, including object-oriented design, data structures, computer systems, and networks. The course focuses on hands-on activities with focus on writing code that implements concepts discussed and on gaining initial exposure to common operating systems, enterprise architectures, and tools commonly used by IT professionals.		
IDS302	DATABASE DESIGN AND PROGRAMMING	4
This course provides students with the technical skills required to design and implement a database solution using an SQL server. Students use data definition language (DDL) to create and delete database objects and data manipulation language (DML) to access and manipulate those objects. Students gain hands-on experience with database design, data normalization, SQL sub-queries, creating and using views, understanding and working with data dictionaries, and loading and unloading databases. Practical activities focus on writing code that implements concepts discussed in the lecture course, specifically creating databases and SQL queries.		
IDS303	LINEAR ALGEBRA	3
This is a basic subject on matrix theory and linear algebra. Emphasis is given to topics that will be useful in other disciplines, including linear algebra, mathematical analysis, and calculus of operations, line geometry, topology, and matrix theory, systems of equations, vector spaces, system determinants, eigenvalues, similarity, and positive definite matrices. The course also includes Graphs and Networks; Systems of Differential Equations; Markov processes, Least		

Squares and Projections; and Fourier Series and the Fast Fourier Transform, differential equations. This course is intended primarily for mathematics, science, and engineering students. The goal of the course is to impart the concepts and techniques of modern linear algebra (over the real scalar field) with a significant level of rigor. Students write clearly about the concepts of linear algebra (definitions, counterexamples, simple proofs), and apply theory to examples. The course emphasizes the practical nature of solutions to linear algebra problems. Students implement some of these solutions, where appropriate, as computer programs.		
IDS304	**PROGRAMMING FOR DATA ENGINEERING: 1**	**3**
The course will introduce the students to programming tools and languages which are used in data engineering domains. The programming and technical know-how imparted for this course would include Core Java and Java Frameworks. The modules covered will include data structures, programming and analysis with Java Interface. Emphasis will be laid on exposing the students to real life case studies and scenarios on application of Java for Data Engineering.		
IDS305	**PRINCIPLES OF DATA ENGINEERING**	**3**
The course will introduce the students to the best practices and principles of Data Engineering. The curriculum will introduce the students to concepts of Entity Relationship, Schemas and other aspects of Data Engineering including integrity, structure, and methodologies for both relational and non-relational components. Other aspects will include data loads and functionalities of analysis.		

SEMESTER 2 **SEMESTER TOTAL CREDITS : 16**

CODE	TOPIC	CREDITS
IDS401	**INTRODUCTION TO COMPUTER ARCHITECTURE**	**3**

This course introduces current trends in computer architecture with a focus on performance measurement, instruction sets, computer arithmetic, design and control of a data path, pipelining, memory hierarchies, input and output, and a brief introduction to multiprocessors. Practical activities focus on writing assembly language code that implements concepts discussed focusing on registers, processes, threads, and I/O management.		
IDS402	**PROGRAMMING FOR DATA ENGINEERING: 2**	**3**
The course will introduce the students to programming tools and languages that are used in data engineering domains. The programming and technical know-how imparted for this course would include Python. The modules covered will include data structures, programming and analysis with Python Interface. Emphasis will be laid on exposing the students to real life case studies and scenarios on application of Python for Data Engineering.		
IDS403	**PROGRAMMING FOR DATA ENGINEERING: 2**	**3**
The course will introduce the students to programming tools and languages which are used in data engineering domains. The programming and technical know-how imparted for this course would include Python. The modules covered will include data structures, programming and analysis with Python Interface. Emphasis will be laid on exposing the students to real life case studies and scenarios on application of Python for Data Engineering.		
IDS404	**ALGORITHMS & DATA STRUCTURES**	**3**
This course covers classical algorithms and data structures (algorithm design and analysis), with an emphasis on implementation and use to solve real-world problems. The course focuses on algorithms for sorting, searching, string processing, and graphs. Students learn basic strategies to characterize and evaluate greedy algorithms, divide-and-conquer, recursive backtracking, and dynamic programming. Practical activities that focus on writing code that implements concepts and focus on algorithm implementation techniques.		
IDS405	**OPERATING SYSTEMS**	**2**
This course explains the concepts, structure, and mechanisms of modern operating systems. The course covers computational resources, such as memory, processors, networks, security, and how the programming languages, architectures, and operating systems interact. Practical activities that focus on writing a shell that implements process management, file management, and I/O management.		
IDS406	**MINI PROJECT & PRESENTATION**	**2**

Every student will be expected to submit a mini project covering the topics and will be making presentation on those topics. The credits will be provided for the content quality of the deliverable.

SEMESTER 3 **SEMESTER TOTAL CREDITS : 16**

CODE	TOPIC	CREDITS
IDS407	**INFORMATION SECURITY**	**2**
This course builds upon knowledge already acquired in the areas of system architecture and operating systems and focuses on the core issues of information security. Students learn fundamental aspects, security mechanisms, operational issues, security policies, attack types, security domains, forensics, information states, security services, threat analysis, and vulnerabilities with some case studies and practical scenarios.		
IDS408	**OBJECT ORIENTED PROGRAMMING**	**3**
This course provides an introduction to object-oriented programming usingthe most current business application programming languages and tools. Students will design, create, run, and debug applications. The course emphasizes the development of correct, well-documented programs using object-oriented programming concepts. Students also learn to create GUI-based programs.		
IDS409	**PRINCIPLES OF COMPILERS**	**3**
This course reviews the concepts and tools used in the development of compilers. Students synthesize topics covered in previous courses: formal languages, data structures, and computer architecture. The course reinforces the principles of software engineering and development through a complete cycle of building a working compiler. The practical activities focus on writing a compiler including a lexer, parser, semantic analyzer, code generator, and optimizer.		
IDS501	**ETL PROCESS**	**3**
This course will cover basic to advance levels of ETL process and would aim at introducing the students to conceptual understanding of ETL and taking them further to providing them with		

hands on ETL process using SQL, Python, and other systems. The course with cover real life case studies and scenarios for ETL process.		
IDS502	**STATISTICAL MODELING AND PREDICTION**	**2**
Students learn to build predictive models with multiple and logistic regression, random forests, and Neural Networks with some data mining techniques and algorithms. They work on data preparation and transformation, data exploration and running descriptive statistics with data followed by generalized linear and nonlinear models, artificial neural networks, and decision trees, probabilities of profit and loss, model validation, comparison and implementation. The course ends with a case study based project with R as the basic programming tool.		
IDS503	**DISTRIBUTED COMPUTER PARADIGMS**	**3**
Introduction to MapReduce and Hadoop, different types of Mappers & Reducers, APIs, and interfaces with sample programs, data manipulation, data flow models, parallel databases, parallel query processing, and in-database analytics, key-value stores and NoSQL systems, effectively write algorithms for systems including Hadoop, YARN and Spark, their limitations, design details, their relationship to databases, and their associated ecosystem of algorithms, extensions, and languages, landscape of specialized Big Data systems for graphs, arrays, streams, and cloud computing.		

SEMESTER 4 **SEMESTER TOTAL CREDITS : 24**

CODE	TOPIC	CREDITS
IDS504	**BIG DATA INFORMATION SYSTEMS**	**4**
This course introduces modern theories, design, and implementation models for large scale text-based information systems. The information retrieval methodologies include Boolean, vector space, probabilistic, inference net, and language modeling. Students will acquire hands-on experience by implementing models such as clustering algorithms, automatic text categorization, and experimental evaluation. Students will experiment with cross-context retrieval algorithms, intelligent text summarization, topic detection, tagging, and tracking. The course also introduces students to unstructured data with Big Data technology such as		

MongoDB. The hands-on activities focus on implementing techniques for efficiently managing and manipulating very large data sets residing in a distributed SQL database.		
IDS505	**SEARCH ENGINE AND DATA MINING**	**4**
This course provides a comprehensive introduction to the location, retrieval, and conversion of raw data into usable information. Students implement algorithms for organizing and searching very large data collections, typically found in enterprise databases and on websites. Students used clustering and categorization to generate various information taxonomies based on document ranking, evaluation, and classification. The practical activities focus on performing data mining on a large business database and extracting trends and actionable information.		
IDS506	**MANAGING BIG DATA**	**4**
Introduction to NoSQL, Hive – architecture, queries development, partitioning and bucketing, key functions and constructs, UDF, UDTF and UDAF, Java API based development of Hive queries, and similar approach with Pig, Sqoop, Impala, HBase, MongoDB, Dynamo, Cassandra, Neo4j, ETL using Hive, Pig and HBase, ETL using MapReduce, working with different file formats and working on platforms such as Cloudera, MapR, and so on.		
IDS507	**ANALYTICS FOR DYNAMIC SOCIAL NETWORKS**	**4**
This course focuses on very large web-based sources of information such as social networks and semantic networks and analysis using Big Data. Students analyze dynamic data and trends, connections (links), and patterns of self-organization. Students then utilize intelligent inferential techniques to interpret patterns in the collected information and translate them into actionable items. Hands-on experiences include marketing, organizational structure, security, and human analytics.		
CAP613	**CAPSTONE PROJECT**	**8**
Capstone project is an extension of Specialization track. Students select a Specialization track followed by related coursework ending with Project presentation relevant to applications of Data Science in Healthcare, Security Intelligence or Forecasting and Econometrics or any area of interest. Instead of Project, Students can optionally pursue, academic research or Thesis followed by a publication with the standards of a scientific journal. They may be required to defend their Thesis.		

Master of Science Programs

Master of Science in Clinical Trial Management

The Master of Science in Clinical Trial Management and Informatics is a highly-selective program for students with a strong background in any biological science area that includes medicine, nursing, dentistry, pharmacy, microbiology, biotechnology, biochemistry, and similar areas. Students with a background in information technology, biostatistics, and other general commerce and finance background can also take this as an additional specialty option after some prerequisite training.

This course provides training for students to learn how the drug development process undergoes experimental evaluation in human beings before the drug gets licensed for marketing. Students will learn about the development of compliant regulatory activities involved in creating documents; and in conducting, recording, monitoring, and reporting clinical trials in human beings. The program provides additional opportunities to learn about recent advancements as well as specializations in a few of the leading subspecialties.

It is designed to delve into concepts of personalized medicine, present an overview of the theory of medical decision-making concepts necessary for performing systemic reviews and meta-analyses, and provide an introduction to writing a grant proposal for the NIH (National Institutes of Health). The course includes extensive practical sessions to provide rigorous hands-on experience in Oracle Clinical, which is the most widely used Clinical Data Management System (CDMS) adopted by the pharmaceutical industry today, and in SAS (Statistical Analysis System). Clinical SAS programming is used for clinical data integration, organizing, standardizing, and managing clinical research data and metadata.

CIP Code: 51.1005
Total Credits: 36
Program Code: MSCTM
Program Mode: Hybrid

Semester 1

MSCTM601 Introduction to Clinical Trials and Application of Regulatory Issues in Clinical Research 3 Credits

This course provides a holistic perspective of clinical research from the preclinical phase through the three phases of clinical research. It introduces practical aspects and key issues in drug development including fundamental concepts of government policies and regulations, the historical development of drug laws, the Food and Drug Administration (FDA); and provides the student with the foundations necessary to build a strong understanding of regulatory affairs. It covers all the different aspects of good clinical practice (GCP) and the inherent risks involved in clinical trials.

MSCTM602 Program Planning and Evaluation 2 Credits

This course provides a comprehensive analysis of the fundamental concepts and activities in the clinical research process including design, conduct, analysis, and interpretation of trial results. It covers the key roles and responsibilities of sponsors, sites, and third-party vendors such as contract research organizations (CROs). Students will be taught about protocol preparation for various phases, methods of randomization, blinding, sample size determination, and endpoint analysis in clinical trials. They will also learn to prepare regulatory submissions including investigational new drug applications (INDs), new drug applications (NDAs), investigator's brochure (IB), and trial master files (TMFs).

MSCTM603 Responsible Conduct of Research 2 Credits

This course examines and evaluates the fundamental principles and processes involved in the monitoring of clinical trials. It provides an overview of the principal investigator's responsibilities of protecting subject rights, safety, welfare, protocol compliance, and adherence to federal regulations and guidance. It also covers the activities of the coordinator such as managing subject enrollment, recruitment, retention, and informed consent procedure, and case report form entry, maintenance of drug inventory site logs, site regulatory files, and safety reporting.

MSCTM604 Regulatory and Ethical Requirements in Clinical Investigations 2 Credits

This course focuses on federal and local regulations and functions to ensure that the rights and safety of research participants are protected. Students will be taught about the practicalities of obtaining grant approvals for regulatory documents such as protocol, informed consent templates, and advertisements for IRB approval. They will also be exposed to the ethical issues surrounding clinical research studies including social accountability, risk-benefit analysis,

vulnerable population, and recruiting strategies. The course also gives students a thorough understanding of the HIPAA Privacy Confidential Act.

BSE616 Basics of Biostatistics and Epidemiology 3 Credits

Students will be exposed to a basic understanding of biostatistics as it is applied in clinical trial data analysis to provide answers to very important questions about efficacy, equivalence, and superiority of investigational medicinal products. The course will also teach students about how various integration methods of data interpretation add value to the outcome of clinical trials.

Semester 2

MSCTM605 MCT Monitoring of Clinical Trials 1 Credit

This course provides a thorough understanding of how a sponsor must organize the in-house monitoring functions to research pharmaceuticals, biologics, and devices. It also teaches students about how a regional CRA supervises, monitors, supports, and carries out activities such as investigational site selection, setup, initiation, monitoring, and close-out; and resolves queries arising because of protocol deviation, AE/SAE, and local site file issues.

MSCTM605 CTF Clinical Trial Functions 2 Credits

This course provides an overview of the planning, execution, and preparation of operational processes such as budgets, contracts, and site logs for clinical trials. It also covers vendor management, which supports systemic quality driven in the selection of vendors, outsourcing agencies, and key challenges in supply chain management. Students will be taught how to prepare various standard operating procedures for sponsors, investigational sites, and institutional review boards; and how to prepare different templates for contracts and monitoring reports.

MSCTM605 SCTS Seibel Clinical Trial Management System 2 Credits

This course provides an overview of clinical trials and clinical trial management from study setup to close out. Topics include managing vendors, investigators, and project management concerns. Students will also learn about important concepts of clinical trial management processes like study planning, site closeout activities, and clinical trip reports.

MSCTM606 Clinical Data Management and Oracle Clinical 3 Credits

This course is designed to provide extensive hands-on training in the niche domain of clinical data management including CRF development, DCF management, and clinical database planning. Clinical data management is the process of collecting, sorting, extracting, and analyzing data generated from clinical trials. Oracle Clinical is the de facto standard for management of this data in the pharmaceutical industry.

PTM617 Project Management **2 Credits**

This course will cover the generic concepts and principles of project management, strategic planning, and leadership in clinical research. Students will learn about the role of the project manager in developing and maintaining the timeline, budget, and quality of a project as well as the principles of project management in clinical research.

LTR618 Literature Review **2 Credits**

This course is designed to train students to conduct a systematic literature review to develop competencies in reading and writing scholarly literature such as research proposals, dissertations, and research papers. Students will also learn about important standards in the arena of literature reviews.

Semester 3

Track 1

MSCTM607 Patient-Reported Outcomes in Clinical Trials **2 Credits**

This course will provide a comprehensive overview of patient-reported outcomes (PRO) in clinical trials. Students will learn how to design and evaluate a PRO questionnaire; what the principles and best practices are for integrating PROs in observational studies, population surveillance, and clinical trials; and develop the skills necessary for evaluating the psychometric properties of a PRO measure. They will also develop a research proposal and present it to the class.

MSCTM608 Special Situations in Clinical Trials **3 Credits**

This course will expose students to special situations in clinical trials including end-points for clinical trials, health-related quality of life trials and instruments, and end-points in immune diseases. Students will also learn about oncology trials, pain management trials, clinical trial designs, blood cancers, and personalized medicine.

MSCTM609 Personalized Medicine **2 Credits**

This course will cover the application of therapeutic drug monitoring (TDM) in the management of patients and how TDM was the earliest form of personalized medicine; explain the nomenclature used to describe genotype and phenotype; and discuss the role of pharmacogenomics in drug therapy for therapeutic areas such as cardiovascular disease, asthma, and hepatitis C. Students will also learn about the ethical, economic, legal, and social issues that frequently arise with pharmacogenomics; and the evolving role of the pharmacist in pharmacogenomics.

MSCTM610 Regulatory Medical and Grant Writing 3 Credits

Students will learn how to develop a strong research project plan for NIH submission; how to prepare templates for pharmacovigilance reports; and how to navigate the grant application process for the National Institutes of Health (NIH) and the NIH's Research Portfolio Online Reporting Tools (RePORT). The course will also teach students about the guidelines for medical writing and the need for regulatory submissions for GCP compliance.

Track 2

MSCTM611 Applied Biostatistics II 2 Credits

This course will cover hypothesis testing, interim analysis in clinical trials I and II, and safety and efficacy evaluations. Students will also learn about P-values, multiple inferences, and linear and logistic regression for various subgroup analysis; and statistical distribution, randomness, validating quantitative tests, and meta-analysis. The course will also cover the overall elements and considerations for clinical trial design.

MSCTM612 Base SAS and SAS Clinical 3 Credits

This course will teach students about the migration (import and export) of clinical data using PROC IMPORT and PROC EXPORT and how data sets are used to import or export files to the FDA using SAS XPORT transport format and to non-FDA organizations using PROC CPORT. Students will also learn about data manipulation techniques using SAS DATA, various statistical procedures for clinical trials, the SAS macro facility, and its components, and the last observation carried forward (LOCF) method in clinical trials.

MSCTM613 Comparative Effectiveness Research 1 Credit

This course defines comparative effectiveness research (CER) and highlights the history and current national efforts in promoting CER for drugs, devices, and other interventions. It covers many important issues in CER, and all aspects of conceptualization, design, sampling, modeling, data collection and analysis used in CER studies. The curriculum was developed to teach students

about research methodology, problems and controversies, and the complexities of designing CER studies.

MSCTM614 Meta-Analysis 1 Credit

This course provides an overview of the concepts necessary for performing meta-analyses as well as the limitations of meta-analysis and how results can be biased. Students will learn how to formulate a specific study question and define specific inclusion and exclusion criteria, and conduct an electronic search using the appropriate terms in a suitable database. They will also learn how to apply the PRISMA checklist to assess the quality of the reporting of a published meta-analysis. The course will also teach students how to run a fundamental analysis of data using STATA and carry out sensitivity analyses and meta-regression in STATA.

MSCTM615 Clinical Decision Analysis 2 Credits

This course will provide an introduction to the use of decision sciences in health care. In addition to developing a conceptual understanding of medical decision-making, the course will emphasize technical skills in decision analysis including the creation and evaluation of decision trees, the use of sensitivity analysis, and the incorporation of particular patient preferences for various interventions and health states. The advantages and disadvantages of formal mathematical models for the analysis of clinical conditions will be presented, and examples from the current medical literature will be discussed.

Track 3

MSCTM611 Applied Biostatistics II 2 Credits

This course will cover hypothesis testing, interim analysis in clinical trials I and II, and safety and efficacy evaluations. Students will also learn about P-values, multiple inferences, and linear and logistic regression for various subgroup analysis; and statistical distribution, randomness, validating quantitative tests, and meta-analysis. The course will also cover the overall elements and considerations for clinical trial design.

MSCTM612 Base SAS and SAS Clinical 3 Credits

This course will teach students about the migration (import and export) of clinical data using PROC IMPORT and PROC EXPORT and how data sets are used to import or export files to the FDA using SAS XPORT transport format and to non-FDA organizations using PROC CPORT. Students will also learn about data manipulation techniques using SAS DATA, various statistical procedures for clinical trials, the SAS macro facility, and its components, and the last observation carried forward (LOCF) method in clinical trials.

MSCTM616 Introduction to SQL **1 Credit**

This course teaches everything one needs to know to start building databases with the SQL server. The course reviews the major features of SQL and shows students how to architect efficient, high-performance solutions for organizations of any scale. Students will learn how to install and configure the SQL server, create databases and tables, automate common tasks like backups, and use the SQL query language to retrieve and manipulate data.

MSCTM617 Data Warehousing and Data Mining **1 Credit**

This course will cover data warehouse and data mining and their applications to business intelligence. Students will learn about requirements gathering for data warehousing, data warehouse architecture, dimensional model design for data warehousing, physical database designs for data warehousing, introduction to business intelligence, design and development of business intelligence applications, expansion and support of a data warehouse, and data mining techniques.

MSCTM618 Tableau **2 Credits**

This course will expose students to the important concepts and techniques used in Tableau to move from simple to complex visualization and teach them how to combine them in interactive dashboards. The course will cover the many options for connecting to data, tableau interface and paradigm components, shelves, data elements, and terminology needed to create the most powerful visualizations efficiently. Basic calculations including string manipulation, basic arithmetic calculations, custom aggregations and ratios, date math, logic statements, and quick table calculations; and the many options for connecting to data.

MSCAP619 Capstone Project **3 Credits**

The course will consist of up to 10 hours of classroom sessions. The students will receive instruction on the research methodology and the form and structure of both the proposal and final project.

Master of Science in Data Science

The Master of Science in Data Science is a highly-selective program for students with a strong background in mathematics, computer science, and applied statistics. The degree focuses on the development of new methods for data science. Building on a core of computer science, information systems, statistics and mathematics, the curriculum will focus on foundations of data science, statistical modeling, data mining, machine learning, business analytics, and scientific visualization.

Specialization tracks include, but are not limited to the fields of healthcare, fraud and security intelligence, and economics and forecasting. A capstone experience, in which students will obtain, condition, explore, model, and interpret a big data set, is central to the degree. Students will have a complete and comprehensive understanding of data science as a whole.

A data scientist formulates a problem, applies the methodology to identify the problem systematically, develops a hypothesis, and designs a study to investigate it. Data scientists also perform data analysis using data exploration techniques and statistical measures, create meaningful data visualizations and models to predict expected future outcomes, and test programs to implement solutions. They are required to present their results in a highly analytical and well-communicated manner.

The question facing every organization today is how to use all data that is relevant and available effectively. The requisite expertise goes beyond traditional statistics and spreadsheet-level modeling. The data science practitioner must holistically approach massive and varied data sources. This reality involves many activities, including finding, conditioning, exploring, warehousing, and modeling of data, as well as the final step of making sense of the data using visualization, machine learning, and statistics, and explaining it to others. The data science degree emphasizes the critical arc that runs from data to information, information to knowledge, and knowledge to decision making.

CIP Code: 11.0401
Total Credits: 36
Program Code: MSIDS
Program Mode: Hybrid

Semester I

Math and Statistics:

MSIDS601 Design and Principles of Research for Data Science **2 Credits**

Data analytic thinking starts with proposing a clear definition of the problem statement to plan solutions in a Data Analytic Format. Evidence-based solutions depend entirely on the acquisition of suitable data resources, understanding the type of data and databases, algorithmic thinking, planning and structuring statistical methodology, decision supporting models and selecting the right tools for data analysis. This module introduces a sequential order of tasks that a data scientist performs to make the best sense of data. It also emphasizes the dire need of communicating results with visualization, storytelling, reports and presentation.

MSIDS602 Mathematical Foundations for the Data Scientist **1 Credit**

Mathematics is indeed the Mother of all Sciences. Mathematical Foundations for the Data Scientist introduces just the required mathematical skills that are relevant to building the framework of data analytic process. The course starts with a refresher on concepts of Number Systems, Linear Equations, Quadratic Equations, Numerical Analysis and Calculus extending to Vectors and Matrix Operations, Complex numbers, Computer-based solution of systems of algebraic equations obtained from engineering problems, Graphing Analysis with Linear Programming, Gaussian Elimination iterative methods, to finding solution of non-linear algebraic equations.

MSIDS603 Introduction to Linear Algebra **1 Credit**

Linear Algebra is one of the most fundamental topics in Mathematics that every Data Scientist should know. This course includes the study of vectors in the plane and space, systems of linear equations, matrices, determinants, vectors, vector spaces, linear transformations, inner products, eigenvalues, and eigenvectors.

MSIDS604 Fundamentals of Applied Statistics **2 Credits**

This course introduces the theoretical concepts of Statistics with programming tools for Data Science. Theoretical Concepts of Data Exploration, Comparison, Theory of Probability, Data distributions, Sample size and Estimation, Univariate, Bivariate and Multivariate analysis, Tests of Hypothesis, Inferences, Contingency tables are introduced with Projects based statistical problem solving with SAS and R programming tools.

Programming:

MSIDS605 Programming with R and SAS **3 Credits**

This course builds upon introduction to R and SAS programming. R data types and objects, Reading, Importing and Writing data, Control Structures, Functions, Data Manipulation, Data exploration, debugging, code profiling, syntax and formats, loops, R Macros, simulation and optimization with R. Data Migration, Manipulation, SAS Functions, Data Exploration, Graphing, Validation and Optimization, SAS Macros, Tabulations and Reporting with Base SAS.

PREQ1 Object Oriented Concepts (Java)

This course aims to review Object Oriented Programming Concepts, mainly in Java. Topics include Environment, Basics, Operators, Java-based Decision Making, and Data Structures. Students would be able to develop high-quality developing software that solves real-world problems and in turn transition to the languages used in Data Science.

Prereq (Mooc) / Summer Courses

PREQ2 Introduction to Databases and Data Warehousing

This course starts with explaining data mining concepts with structured data of Relational databases, semi-structured XML data and getting introduced with unstructured data. Students will also learn SQL as a common language. The course also describes the specific structure of databases in their organization, content and proceeds to an in-depth understanding of data warehousing, requirement gathering, defining the architecture and design of data warehousing, ETL strategies, and Cloud- based computing.

PREQ3 Data Mining Concepts with Relational Databases- Structured Data

Data Mining is the extraction of useful, anonymous data from data in databases. It is also known as KDD (Knowledge Discovery in Databases). The iterative process consists of Data Cleaning, Data Integration, Data Selection, Data Transformation, Data Mining, Data Evaluation, and Knowledge Representation. This course will serve as an introduction to Data Mining with Relational Databases.

Mining Concepts with Relational Databases is a pre-requisite course for many courses in the Data Science Curriculum. Students are expected to present proficiency level in basic SQL with previous Coursework or Certifications.

Semester II

MSIDS606 Introduction to Algorithms for Data Science 3 Credits

Students learn the applications of Asymptotic Analysis, Graphs, Divide and Conquer Algorithms, Data structures, Hash tables, Dynamic Programming, Network Flow, NP-completeness, Randomization Algorithms, Heuristics and Dynamic Programming.

MSIDS607 Data Mining Concepts with Semi-Structured Data/XML 2 Credits

Semi-Structured Data is a form of structured data that does not conform to traditional data models. XML is widely used for Semi-Structured Data. A brief review of Data Mining Concepts would be discussed, which would lead to indexing XML data, transforming relational data to XML data, mining association rules, among other topics.

MSIDS608 Statistical Modeling & Prediction 2 Credits

Students learn to build predictive models with logistic regression, random forests, and Neural Networks. They work on data preparation and transformation, data exploration and running descriptive statistics with data followed by generalized linear and nonlinear models, artificial neural networks, and decision trees, probabilities of profit/loss, model validation, comparison and implementation. The course ends with a case study-based project with SAS and R as the basic programming tools.

LTR618 Literature Review 2 Credits

This course is designed to train students in the conduct of a systematic literature review and to develop the skills to conduct a review, to develop competencies in reading and writing scholarly literature, such as research proposals, dissertations, and research papers and to know about exceptional standard in the arena of literature reviews.

Data Visualization:

MSIDS609 Data Visualization and Communication 2 Credits

This course focuses on data representation with visualizations, reporting, communication and storytelling with industry tools like SAS Visual Analytics and TIBCO spot fire. Students work on importing data, data sources, interpret the chart, graph and table visualizations, edit, modify and create reports, share reports and finally prepare project presentation of case studies with static and dynamic presentations.

MSIDS610 Information Retrieval, Web and Text Analytics 1 Credit

Students learn about using textual data for data exploration and predictive modeling, cluster, and subgroup data, perform a term-based and string-based search with query filters and create rule-based statistical models for predicting customer's sentiments and categorizing documents as per taxonomy using SAS programming. Students are also introduced to the deep knowledge of web analytics and web intelligence, interpreting key web metrics and KPIs for optimizing website design and online marketing.

Prereq (Mooc) / Summer Courses Computing:

PREQ4 Cloud Computing & Big Data

Cloud computing and Big Data work together to store, process, analyze, access and report information. Analytical techniques can apply on a much grander, faster scale and can be more accessible to users. Topics discussed include Data Elements, Aggregates, Clusters, and Risks of using Big Data with Cloud Computing along with common industry issues in Dimensions of Data Quality such as relevance, accuracy, timeliness, coherence, security, and validity.

This is an optional course in the Data Science Curriculum. Students are expected to present proficiency level with previous Coursework or Certifications.

Semester III

Machine Learning:

MSIDS611 Applied Machine Learning 3 Credits

Applied Machine Learning focuses on writing computer programs that help the computer to present calculated inferences from examples or previous instances rather than a set of rules formulated by syntaxes. This course introduces the theoretical basis of Supervised and Unsupervised Learning with an understanding on conceptualizing a problem, representing data, interpreting results and error handling with error analysis to make judgment on adjusting the data and selecting the algorithms for making the right decisions. The course ends with case study, projects and programming assignments with SAS and R programming, to provide practical exposure.

MSIDS612 Mining Massive Datasets/Data Mining Concepts with Un-Structured Data/Hadoop 3 Credits

Distributed le systems: Hadoop, map-reduce; PageRank, topic-sensitive PageRank, spam detection, hubs-and-authorities; similarity search; shingling, mind hashing, random hyperplanes, locality- sensitive hashing; analysis of social-network graphs; association rules; dimensionality reduction: UV, SVD, and CUR decompositions; algorithms for very-large-scale mining: clustering, nearest-neighbor search, gradient descent, support vector machines, classification, and regression; submodular function optimization.

MSIDS613 Predictive Analytics with SAS 3 Credits

This hands-on course will cover concepts of theory and application of methods and models used for predictive analytics. Topics may include regression analysis, neural networks, random forest, predictive modeling and various Statistical regression methods. Gain a fundamental understanding of Predictive Analytics so that Students will be able to produce a full data set compatible for building predictive dynamic models using Mathematical and Statistical concepts.

MSIDS614 Specialization Track 3 Credits

Specialization track consists of three tracks-

Track 1: Healthcare
Track 2: Fraud and Security Intelligence
Track 3: Forecasting and Econometrics

Students are given the option to choose any one of the tracks to receive three credits.

Track 1: Healthcare

In this track students are given the opportunity to choose any one module from the following:
MSIDS614DSA Drug Safety Analytics and Signal Detection
MSIDS614CTA Clinical Trial Analytics
MSIDS614DAE Design and Analysis of Epidemiological Studies

MSIDS614DSA Drug Safety Analytics and Signal Detection

Business intelligence and analytics have come a long way to provide essential tools for pharmaceutical and contract research organizations. Students learn the applications of analytics in conquering and optimizing adverse events, on data acquisition and case volume management, case processing, adverse and non-adverse event tracking and finally cause analysis that helps companies to take timely actions. Students will have a hands-on experience with Oracle Argus

and SAS to extract drug safety data from various databases on ETL programs and run analytical procedures to prepare reports for regulatory needs.

MSIDS614CTA Clinical Trial Analytics

This course introduces students to clinical trials with a detailed view of all the phases of clinical trial studies, the design of experiments, types of clinical data, data integration and manipulation with a special emphasis on planning statistical analysis tests, preparing tables, listings, graphical outputs and reports for regulatory submissions using SAS.

MSIDS614DAE Design and Analysis of Epidemiological Studies

Students with a background in Epidemiology or Public Health and Biostatistics learn about designing epidemiological studies, survey designs, conducting analytical studies with info to read data and run detailed epidemiological statistics, tables, maps, and graphs. SAS is also used on case study based projects where students are exposed to real-world design, planning, and analysis of epidemiological studies.

Track 2: Fraud and Security Intelligence

MSIDS614FSI Fraud and Security Intelligence

Fraud and Security Intelligence discusses the effective methods of identifying fraudulent individuals with data and social network information exploration with SAS Fraud Framework. It also introduces the main concepts, terminology, base functionality related to SAS Anti-money Laundering, further going into the details of transaction monitoring investigations, conducting in-depth searches of customer activity, adding information to alerts and cases, and viewing reports. Analysts, Investigators, and Managers benefit greatly with this preparation.

Track 3: Forecasting and Econometrics

MSIDS614FAE Forecasting and Econometrics

This course is based on teaching students how to use their quantitative, statistical, and analytical skills to solve business problems with basic foundations of building and using econometric models, making strong prediction-based forecasts, and perform econometric analysis with SAS. Students work on proposing solutions by creating and fitting custom forecast models to full-time series data sets, testing and improving forecast efficiency, performing data updates on large time-series data sets. Students learn about the techniques of business improvement by using social media as a tool for brand management.

Semester IV

CAP619 Capstone Project **3 Credits**

The Capstone project is an extension of the Specialization track, as mentioned above. Students select a specialization track followed by related coursework ending with a project presentation relevant to applications of Data Science in Healthcare, Security Intelligence or Forecasting and Econometrics or any area of interest. Instead of the project, students can optionally pursue, academic research or thesis followed by a publication with the standards of a scientific journal. They may be required to defend their thesis.

Master of Science in Drug Safety and Pharmacovigilance

The Master of Science in Drug Safety and Pharmacovigilance program is well-suited for students with a strong background in fields like medicine, dentistry, pharmacy, nursing, biostatistics, computer and information technology, or a degree equivalent to the above in another subject and a portfolio demonstrating suitability for study. The program will cover the core knowledge of the drug safety and pharmacovigilance process, as well as a specialization in either causality evaluation with training in MedDRA and medical narrative writing or signal evaluation with training in SAS JMP Clinical and Oracle Analytics, Argus, and Empirica.

With a surge in the advancements of the pharmaceutical industry, regulatory authorities are constantly striving to safeguard the public health, striking a delicate balance between the promising benefits of drugs and varying levels of suspicion about the potential harm. Pharmacovigilance has become cardinal. There is a growing need for qualified professionals for the pharmaceutical industry, regulatory authorities, and academia.

This program will focus on the regulatory issue and requirements across global government agencies that improve safety by covering topics such as Regulatory Compliance for Drug Safety and Pharmacovigilance; and Risk Management, Signal Evaluation, and Reports. Successful navigation of drug safety and pharmacovigilance are keys to product longevity, consumer confidence, and regulatory compliance.

CIP Code: 51.9999
Total Credits: 36
Program Code: MSDSP
Program Mode: Hybrid

Semester I

MSDSP601 Introduction to Drug Safety and its Regulations 3 Credits

Drug development is the process of bringing a new pharmaceutical drug to the market once a lead compound has identified through the process of drug discovery. It includes preclinical research on animals, clinical trials on humans, and the step of obtaining regulatory approval to market the drug. This module will educate students about the basic process of development and the regulatory and compliance processes that ensure consumer safety.

MSDSP602 Organization and Functions of Drug Safety Department 3 Credits

Prescription drugs are crucial for preventing and treating diseases and improving the public's health, but no drug molecule is considered safe unless it proves itself time and again. Hence, watchfulness is mandatory to ensure the safety of the consumers. This process is known as drug safety and pharmacovigilance. The ethical issues of business and medicine have become complicated and challenging. The world of big business has now caught up with big medicine. This module will educate students about the business dynamics of the pharmaceutical industry and the ethics, structure, function of the drug safety department, and its training.

MSDSP603 Regulatory Compliance for Drug Safety and Pharmacovigilance 3 Credits

The discipline of pharmacovigilance and drug safety is highly regulated with ever-changing laws and regulations. The World Health Organization (WHO), all national regulators and health agencies and pharmaceutical companies need to communicate with each other to ensure the global safety of every product in the market. This module educates students about the regulatory functions of pharmacovigilance and the manner in which they operationalize.

MSDSP604 Adverse Events Reporting and Postmarketing Activities 3 Credits

Pharmacovigilance assesses the safety profile of drugs. It is the science related to the collection, detection, assessment, monitoring, and prevention of the adverse effects of pharmaceutical products. Its primary aim in post-marketed drugs is the increase of spontaneous reporting of adverse drug reactions. This module will provide the opportunity to understand the mechanism of the development of adverse events and the vigilance process for the event. This module analyzes the adverse events and explains adverse drug reaction about the drug consumer. This module further addresses the knowledge and methods of evaluating, reviewing, and analyzing the reports of adverse events.

Semester II

MSDSP605 Introduction to Oracle Argus Safety Application Part I 3 Credits

The course provides training to the students on the features of Argus Safety, its role in fulfilling the pharmaceutical industry's toughest regulatory challenges, and how it supports drug safety business processes from an easy-to-understand user interface. Thorough case processing and discussions will allow students to gain skills regarding handling different types of cases, case processing in the software, and the highest possible quality standards to support accurate detection and analysis of drug safety signals.

BSE616 Basics of Biostatistics and Epidemiology 2 Credits

Students will learn the basic concepts of biostatistics and understand how this knowledge is useful for epidemiologic applications in clinical trials as well as healthcare sectors. Students will learn the basic concepts of epidemiology- the science of diseases in populations; and how biostatistics becomes the language of epidemiology to collect, organize, analyze, interpret the data, and its proper use for healthcare and clinical trial forecasting and regulatory issues.

LTR618 Literature Review 2 Credits

This course is designed to train students in the conduct of a systematic literature review and develop the skills to undertake a study to develop competencies in reading and writing scholarly literature, such as research proposals, dissertations, and research papers. The course will also expose students to important standards in the arena of literature reviews.

Electives:

PTM617 Project Management for Drug Safety Professionals 2 Credits

This course will introduce the generic concepts and principles of project management, strategic planning, and leadership in clinical research. The course will cover the full lifecycle of a project including project initiation, planning, execution, control, and closeout; and define the role of a project manager in developing and maintaining the timeline, budgets, and quality of a project. Students will be exposed to the principles of project management processes as applied to clinical research. They will also learn about the tools and techniques of scope, time, cost, quality, risk, human resource procurement, and stakeholder's management.

MSDSP606 Advanced Drug Safety Vigilance 2 Credits

This course covers pharmacovigilance processes in biologically active products, vaccines, invitro diagnostics, and medical devices; pre- and post-market vigilance scenarios in these fields; regulatory evaluation processes; and post-market actions including withdrawal of the product. The course will also cover emerging personalized medication molecules and the ethical and evolving regulatory issues that surround them.

Semester III

MSDSP607 Risk Management, Signal Evaluation, and Reports 3 Credits

One of the most important and challenging problems in pharmacovigilance is that of the determination of causality. Causality may be determined at the individual case level or in aggregate data. This module will educate students about the process of coding, causality assessment, signal evaluation, quality analysis, and reporting to regulatory authorities.

Electives: Track 1

MSDSP608 Introduction to Drug Safety Physician Functions: MedDRA, ADR, Narrative Writing Part I 3 Credits

The pharmacovigilance function centered on assigning causality to an adverse event through medical review. This module will educate students about the process of coding with MedDRA and medical narrative writing in general as well as the ADR of various systems.

MSDSP609 Drug Safety Physician Functions in Pharmacovigilance: Narrative Writing Part II 3 Credits

Causality evaluation starts with narrative writing that involves expressing the messages clearly and efficiently while collating the relevant information from various sources and using medical expertise to scrutinize the information. A narrative tells the complete story chronologically and holds together medically. Identifying and relating the relevant medical history or laboratory result to the event of interest can be challenging. This module will educate students about the process of medical narrative writing in the ADR of various systems and will make them aware of recent advances in the area of adverse drug reactions in different systems.

Track 2

MSDSP610 Oracle Argus Safety Application Part II 3 Credits

Students will learn about the configuration of products, and how licenses are authorized in the various countries. Products and licenses act as the main pillars of Argus Safety and help in the scheduling of reports and in fulfilling regulatory obligations. The course will also address the preparation of periodic reports and extraction of case listings, which are helpful in the critical analysis of the risk- benefit evaluation of drugs**.**

MSDSP611 Signal Detection Using Empirica 2 Credits

The signal detection course shall cover a myriad of topics from detecting signals through validation and confirmation, analysis, prioritization, and assessment to recommending action. The course will also teach students how to track steps taken and make recommendations.

MSDSP612 Signal Detection UsingJMP Clinical 2 Credits

This module provides the opportunity for students to learn about JMP Clinical and get the hands-on training necessary to analyze drug safety databases and support the analytical review function.

MSDSP613 Analytics in Pharmacovigilance 1 Credit

Argus Insight

Argus Insight, formerly called Power Reports, is a highly optimized reporting module that complements Argus Safety. The Argus Insight Extract Transform and Load (ETL) engine extracts data from the Argus Safety database and populates a data warehouse in a format that allows efficient querying. The query, drill-down, and output components of Argus Insight allow it to analyze safety, workflow, or product data from all angles and produce reports that provide immediate business impact and maximum efficiency in decision-making.

Argus Analytics

With the Oracle Argus Analytics software tool, pharmaceutical companies and contract research organizations (CRO) can keep tabs on how efficiently case processing performed, their overall safety compliance with regulatory authorities, and a day-to-day assessment of the drug safety personnel required to maintain a smooth operation of the drug safety department.

Oracle Argus Analytics also functions as a decision support system to monitor process bottlenecks and compliance deviations. Oracle Business Intelligence Enterprise Edition (OBIEE) can integrate

with the existing Argus Safety application. The interactive OBIEE dashboard will provide solutions to business questions and present data in charts, pivot tables, and reports.

Semester IV

DSP614 Recent Advances: REMS, Action, and Drug Withdrawals 3 Credits

Risk Evaluation and Mitigation Strategies (REMS) is a safety strategy to manage a known or potentially serious risk associated with a drug, and to enable pharmaceutical companies to have continued risk evaluation of such medicines and maintain their safe use. This module provides an understanding of the implementation of the regulatory and voluntary, proactive actions required to be implemented by pharmaceutical companies to mitigate safety issues that arise out of reports and are needed for the continued safety of the drug to remain on the market.

CAP619 Capstone Project 3 Credits

The course will consist of up to 10 hours of classroom sessions. The students will receive instruction on the research methodology and the form and structure of both the proposal and final project.

Certificate Programs

Advanced Clinical Research

The Advanced Clinical Research program provides training for students to learn how the clinical trial management process works. Students will learn about the development of complete regulatory activities involved in creating documents; and in planning, organizing, monitoring, recording, analyzing, and reporting of clinical trials in human beings.

The program covers various aspects of a clinical trial from site selection to closeout including advertisement; patient recruitment; important documents; roles and responsibilities; and study conduct, its implementation, adverse events, potential liability and regulations, and its guidelines.

CIP Code: 51.1005
Program Hours: 150 Clock Hours
Program Code: SCCPACR100
Program Mode: Hybrid

Program Curriculum

Theme: Clinical Trial Management

Study Start-Up

Module 1
- Phases of the Clinical Trial
- ICH-GCP Guidelines
- Study Feasibility Site Selection

Module 2
- IRB/IEC
- Budgets
- Contracts

Module 3
- Essential Documents (Prior to Study Start)
- Financial Disclosure Form
- Clinical Trial Protocol

Module 4
- Investigator Brochure
- Informed Consent Process
- Monitoring – General introduction to all the types of visits

Study Conduct

Module 5
- Site Monitoring Visits (Include Remote/Central Risk-Based Monitoring Concept)
- Randomization/Blinding
- Recruitment/Retention/Compliance

Module 6
- Adverse Events/Serious Adverse Events
- Drug Advertisement
- HIPAA Regulations

Module 7
- Medical Devices
- Fraud/Misconduct/Potential Liability

Module 8
- FDA Inspection
- Essential Documents (During Study Conduct)

Study Close Out

Module 9
- Site Close-Out Visit (On-Site/Remote Activities)
- Statistical Analysis

Module 10
- Investigational Drug Application
- New Drug Application
- eCTD (Common Technical Document)

Module 11
- Essential Documents (After Study Close-Out)
- Risk-Based Monitoring

Module 12
- Evidence Based Medicine
- Personalized Medicine
- Big Data

Advanced Drug Safety and Pharmacovigilance

The Advanced Drug Safety and Pharmacovigilance program is a very unique job-oriented training program. The program provides a thorough understanding of the basic concepts of drug safety and risk management throughout the process of drug development and its life cycle in the open market either as a patent or generic drug. This exposure prepares students to understand and appreciate the various types and grades of Adverse Events.

Students are trained to correlate the Adverse Event with any vital and systemic abnormality resulting from this and understand the causal relation of the drug known as Adverse Drug Reaction (ADR). This training further builds the analytical skills needed to differentiate between

the progress of the disease and ADR as a signal. This program will focus on the regulatory issues across global governmental agencies like the FDA, EMA, ICH, and others that improve safety.

Practical training will also be provided on industry-based tools on topics such as data entry, case processing, MedDRA and WHO-DD coding, SAE narrative writing, and signal detection. Students will be trained on how to use programming tools such as Oracle Argus Safety and Oracle Empirica Signal, the market leaders in software programs used to support the entire spectrum of drug safety functions.

CIP Code: 51.9999
Program Hours: 300 Clock Hours
Program Code: SCCPADSP100
Program Mode: Hybrid

Program Curriculum

Module 1: Introduction to Drugs, Safety and its Regulations

Topics covered in this session include the following:

1. Drug Development Process
2. Ethics of Human Subjects Protection
3. Good Clinical Practice in Clinical Trials

Drug development is the process of bringing a new pharmaceutical drug to the market once a lead compound has been identified through the process of drug discovery. It includes preclinical research on animals, clinical trials on humans, and the step of obtaining regulatory approval to market the drug. This module will educate students about the basic process of drug development and the regulatory and compliance processes that ensure consumer safety.

Module 2: Organization and Functions of Drug Safety Department

Topics covered in this session include the following:

1. Ethics, Honesty, and Business Dynamics at Play
2. Understand Drug Safety Department
3. Training in Drug Safety Career for New Hire

The ethical issues of business and medicine have become complex and difficult. The world of big business has now caught up with big medicine. This module will educate students about the

business dynamics of the pharmaceutical industry and the ethics, structure, and function of the drug safety department and its training.

Module 3: Regulatory Compliance for Drug Safety and Pharmacovigilance

Topics covered in this session include the following:

1. Pharmacovigilance and Regulatory Needs
2. US FDA : Regulatory Scenario
3. Europe, ICH, CIOMS, and International Regulatory Scenario

The discipline of pharmacovigilance and drug safety is highly regulated with ever changing laws and regulations. The World Health Organization (WHO), all national regulators and health agencies, and pharmaceutical companies need to communicate with each other to ensure the global safety of every product on the market. This module educates students about the regulatory functions of pharmacovigilance and the manner in which they operationalize.

Module 4: Adverse Events Reporting and Post-marketing Activities

Topics covered in this session include the following:

1. Adverse Events-1 In Detail
2. Adverse Events-2 MedWatch, Voluntary Reports
3. Adverse Events-3 Triage and ICSR Generation

Pharmacovigilance assesses the safety profile of drugs. It is the science related to the collection, detection, assessment, monitoring, and prevention of the adverse effects of pharmaceutical products. This module will provide the opportunity to understand the mechanism of the development of adverse events and the vigilance process for the event. This module analyzes the adverse events and explains adverse drug reaction in relation to the drug consumer. This module further addresses the knowledge and methods of evaluating, reviewing, and analyzing the reports of adverse events.

Module 5: Introduction to Oracle Argus Safety Application I

Topics covered in this session include the following:

1. Pharmacovigilance Overview
2. Regulatory Guidelines
3. Argus Safety Overview
4. Argus Safety Database
5. Case Processing in Argus Safety
6. MedDRA and WHO-DD Overview

The course provides training to the students on the features of Argus Safety, its role in fulfilling the pharmaceutical industry's toughest regulatory challenges, and how it supports drug safety business processes from an easy-to-understand user interface. Thorough case processing and discussions will allow students to gain skills regarding handling different types of cases, case processing in the software, and the highest possible quality standards to support accurate detection and analysis of drug safety signals.

Module 6: Signal Detection Using Empirica

Topics covered in this session include the following:

1. Signal Detection Overview
2. Empirica Signal Introduction
3. Creating Data Mining Runs
4. Empirica Topics and Workflow Configuration
5. Compliance Requirement
6. Master in Data Mining Runs and Sector Map

The signal detection course shall cover a myriad of topics from detecting signals through validation and confirmation, analysis, prioritization, and assessment to recommending action. The course will also teach students how to track steps taken and make recommendations.

Advanced Graduate Certificate in Clinical Trial Management

The Advanced Graduate Certificate in Clinical Trial Management is a highly selective program for students with a strong background in any biological science area that includes medicine, nursing, dentistry, pharmacy, microbiology, biotechnology, biochemistry, and similar areas. Students with a background in information technology, biostatistics, and other general commerce and finance background can also take this program.

This program provides training for students to learn how the drug development process undergoes experimental evaluation in human beings before the drug gets licensed for marketing. Students will learn about the development of regulatory compliant activities involved in creating documents; and in conducting, recording, monitoring, and reporting clinical trials in human beings.

It is designed to provide students with the basic concepts of drug discovery and the tools that are used in drug discovery. Students will learn about the roles and responsibilities of sponsors, principal investigators, and regulators in clinical trials. They will prepare budgets, contracts, and

financial disclosure documents required for ongoing trials. They will understand ethics, federal regulations, good clinical practice (GCP), and how the Food and Drug Administration (FDA) regulates the drug commercialization process.

Students will receive extensive practical sessions to provide rigorous hands-on experience in Oracle Clinical, which is the most widely used Clinical Data Management System (CDMS) adopted by the pharmaceutical industry today, and in SAS (Statistical Analysis System). Clinical SAS programming is used for clinical data integration, organizing, standardizing, and managing clinical research data and metadata.

CIP Code: 51.1005
Program Hours: 960 Clock Hours
Program Code: AGCCTM
Program Mode: Hybrid

Program Curriculum

Module I

CTM 601 Study Start- up

Study Startup is the first step in conducting Clinical Trials. Study startup dives into topics to help the learner understand the phases of the Clinical Trial, ICH-GCP guidelines, Study Feasibility and Site Selection. The student learns about the IRB/IEC, Clinical Trial Budgets and Contracts, Essential documents maintained by the Trial Site and Sponsor, Financial Disclosure Form and Clinical Trial Protocol, Investigator's Brochure, the Informed Consent Process, and Monitoring.

CTM 602 Study Conduct

Study Conduct is the next step in the CTM program. Students learn about Site Monitoring Visits which include Remote and Central Risk-Based Monitoring concept. How and why Randomization and Blinding are done during Clinical Trials. Learn about Recruitment, Retention and Compliance of patients in the Trials, Adverse Event and Serious Adverse Event reporting guidelines, Drug Advertisement, HIPAA Regulations, and ICH GCP guidelines to appreciate US FDA Regulations and Medical Devices. Students also learn about FDA Inspections, Fraud, Misconduct and Potential Liability.

Students get the overview of ePatient Diary, ePRO, eSource, eConsent, eCRF, eISF, eTMF, EHR, EDC, CTMS and similar newer concepts of Risk based Monitoring.

CTM 603 Study Close-out

Study Closeout is the last part that is done during the Clinical Research Program. Students learn about the study close out functions that involves topics like Site Close Out Visit including both On-Site and Remote activities, Site Summary Analysis is required from the Sites to understand the data acquired. Students will learn to understand the Investigational New Drug and the New Drug Application Process as well as the electronic Common Technical Document, to make sure the Essential Documents after Study Closeout have been filed and submitted properly.

Module II

CTM 605 Clinical Data Management and Oracle Clinical

This course is designed to provide extensive hands-on training in the niche domain of clinical data management including CRF development, DCF management, and clinical database planning. Clinical data management is the process of collecting, storing, cleaning, extracting, and analyzing data generated from clinical trials. Oracle Clinical is the de facto standard for management of this data in the pharmaceutical industry.

PTM606 Project Management

This course will cover the generic concepts and principles of project management, strategic planning, and leadership in clinical research. Students will learn about the role of the project manager in developing and maintaining the timeline, budget, and quality of a project as well as the principles of project management in clinical research.

LTR 607 Literature Review

This course is designed to train students to conduct a systematic literature review in order to develop competencies in reading and writing scholarly literature such as research proposals, dissertations, and research papers. Students will also learn about important standards in the arena of literaturereviews.

Module III

Track 1

CTM 608 Risk Based Monitoring

Risk Based Monitoring model and FDA, EMA guidance as well as the ICH E6 R2 guidance are all encouraging this shift toward a leaner, more cost effective, and targeted, risk-based approach towards monitoring that would cover diverse aspects of RBM, including Risk Identification, Evaluation, Control, Review and Reporting, vendor selection, QbD and The Site Perspective of RBM. It will touch upon FMEA, KRIs, the RACT, existing models of monitoring, and why regulators are supporting an RBM approach.

CTM 609 Ethics and Safety Compliance in Clinical Trials

This module provides training in ethics evolution, and the resultant regulatory compliance for safety of the subjects participating in conduct of the trial. This will train students in thorough understanding of correlating various ethics principles while implementing GCP rules with special emphasis on IRBs role in trial safety, approval guidelines, and methods for vulnerable subjects and in different types of trials.

CTM 610 Quality Management and Audits in Clinical Trials

This module will provide detailed learning opportunity about the quality management function of the sponsor for the trial. The basic concept of GxP audit will elaborate the spectrum of Good Laboratory- Clinical- Manufacturing-Practices through the length of the conduct of the clinical trial. It will also encompass the FDA audit query resolution process.

Track 2

CTM 608 Risk Based Monitoring

Risk Based Monitoring model and FDA, EMA guidance as well as the ICH E6 R2 guidance are all encouraging this shift toward a leaner, more cost effective, and targeted, risk-based approach towards monitoring that would cover diverse aspects of RBM, including Risk Identification, Evaluation, Control, Review and Reporting, vendor selection, QbD and The Site Perspective of RBM. It will touch upon FMEA, KRIs, the RACT, existing models of monitoring, and why regulators are supporting an RBM approach.

CTM 611 Medical and Regulatory Writing in Clinical Trials

This module provides training in preparation of various essential documents like Investigator's brochure, Protocol, Informed consent and other documents. It will expose students to the concept of Site File, Sponsor's Trial Master File along with IND/NDA submission process and CTD.

Track 3

CTM 608 Risk Based Monitoring

Risk Based Monitoring model and FDA, EMA guidance as well as the ICH E6 R2 guidance are all encouraging this shift toward a leaner, more cost effective, and targeted, risk-based approach towards monitoring that would cover diverse aspects of RBM, including Risk Identification, Evaluation, Control, Review and Reporting, vendor selection, QbD and The Site Perspective of RBM. It will touch upon FMEA, KRIs, the RACT, existing models of monitoring, and why regulators are supporting an RBM approach.

CTM 612 Applied Biostatistics II

This course will cover hypothesis testing, interim analyses in clinical trials I and II, and safety and efficacy evaluations. Students will also learn about P-values, multiple inferences, and linear and logistic regression for various subgroup analysis; and statistical distribution, randomness, validating quantitative tests, and meta-analysis. The course will also cover the overall elements and considerations for clinical trial design.

CTM 613 Base SAS and SAS Clinical

This course will teach students about the migration (import and export) of clinical data using PROC IMPORT and PROC EXPORT and how data sets are used to import or export files to the FDA using SAS XPORT transport format and to non-FDA organizations using PROC CPORT. Students will also learn about data manipulation techniques using SAS DATA, various statistical procedures for clinical trials, the SAS macro facility and its components, and the last observation carried forward (LOCF) method in clinical trials.

Module IV

CTM 604 Internship

Students will have a unique hands-on training opportunity with Clinical Trial Management (CTM) system, Electronic Data Capture (EDC) management system, and Electronic Trial Master File (TMF) management system. This will be done through real time case scenarios, clinical tasks, and other site management activities taught by industry experts.

The CTM system is used to prioritize site management activities, update site staff information, document site visits, generate visit tasks and reports, regulatory approval and investigation payment. The EDC systems are used to enter and verify the Case Report Forms (CRF), raise and answer queries, and generate EDC reports. The Trial Master File (TMF) is used to upload and index documents, use naming conventions and electronically sign the documents before submitting. Students work with document Place Holders, Signature Work Flows, TMF Metrics to successfully perform Site Master File and Trial Master File reconciliations.

Module V

- Assignments
- Quizzes
- Lab hours
- Career sessions
- Soft skills

Advanced Graduate Certificate in Data Science

The Advanced Graduate Certificate in Data Science program is a highly selective program for students with a strong background in mathematics, computer science, and applied statistics. The curriculum will focus on foundations of data science, statistical modeling, data mining, machine learning, business analytics, and scientific visualization.

Data scientists excel at analyzing data, particularly large amounts of data, to help businesses gain a competitive edge. A data scientist formulates a problem, applies a methodology to identify the problem, develops a hypothesis, and designs a study to investigate the problem. Students will learn how to formulate appropriate analytic approaches for a problem, collect data with predictive modeling techniques, and come up with solutions for resolving data quality issues.

Students will learn to implement algorithms for data aggregation, cleaning, and analysis. They will also be able to communicate statistical inferences effectively by storytelling and data visualization. Furthermore, students will work with the biggest tools in the industry including SAS, Oracle Argus, R, Hadoop, Map Reduce; mathematical languages like MATLAB and Maple; and object-oriented languages such as Java and Python. They will be able to select and apply appropriate data analysis techniques to a variety of tasks, including Big Data sets.

The program aims at equipping students with the highly specialized skill sets that are necessary for them to make intelligent decisions in data science. Thus, it emphasizes the critical arc that runs from data to information, information to knowledge, and knowledge to decision making.

CIP Code: 11.0401
Program Hours: 960 Clock Hours
Program Code: AGCDS
Program Mode: Hybrid

Program Curriculum

Module I

Math and Statistics:

DS601 Design and Principles of Research for Data Science

Data analytic thinking starts with proposing a clear definition of the problem statement to plan solutions in a Data Analytic Format. Evidence-based solutions depend entirely on the acquisition of suitable data resources, understanding the type of data and databases, algorithmic thinking, planning and structuring statistical methodology, decision supporting models and selecting the right tools for data analysis. This module introduces a sequential order of tasks that a data scientist performs to make the best sense of data. It also emphasizes the dire need of communicating results with visualization, storytelling, reports, and presentation.

DS602 Mathematical Foundations for the Data Scientist

Mathematics is indeed the Mother of all Sciences. Mathematical Foundations for the Data Scientist introduces just the required mathematical skills that are relevant to building the framework of data analytic process. The course starts with a refresher on concepts of Number Systems, Linear Equations, Quadratic Equations, Numerical Analysis and Calculus extending to Vectors and Matrix Operations, Complex numbers, Computer-based solution of systems of algebraic equations obtained from engineering problems, Graphing Analysis with Linear Programming, Gaussian Elimination iterative methods, to finding solution of non-linear algebraic equations.

DS603 Introduction to Linear Algebra

Linear Algebra is one of the most fundamental topics in Mathematics that every Data Scientist should know. This course includes the study of vectors in the plane and space, systems of linear equations, matrices, determinants, vectors, vector spaces, linear transformations, inner products, eigenvalues, and eigenvectors.

DS604 Fundamentals of Applied Statistics

This course introduces the theoretical concepts of Statistics with programming tools for Data Science. Theoretical Concepts of Data Exploration, Comparison, Theory of Probability, Data distributions, Sample size and Estimation, Univariate, Bivariate and Multivariate analysis, Tests of Hypothesis, Inferences, Contingency tables are introduced with project-based statistical problem solving with SAS and R programming tools.

Programming:

DS605 Programming with R

This course builds upon introduction to R programming. R data types and objects, Reading, Importing and Writing data, Control Structures, Functions, Data Manipulation, Data exploration, debugging, code profiling, syntax and formats, loops, R Macros, simulation and optimization with R.

DS606 Object Oriented Concepts (Java)

This course aims to review Object Oriented Programming Concepts, mainly in Java. Topics include Environment, Basics, Operators, Java-based Decision Making, and Data Structures. Students will be able to develop high-quality developing software that solves real-world problems and in turn transition to the languages used in Data Science.

Pre req (Mooc) / Summer Courses

DS607 Introduction to Databases and Data Warehousing

This course starts with explaining data mining concepts with structured data of Relational databases, semi-structured XML data and getting introduced with unstructured data. Students will also learn SQL as a common language. The course also describes the specific structure of databases in their organization, content and proceeds to an in-depth understanding of data warehousing, requirement gathering, defining the architecture and design of data warehousing, ETL strategies, and Cloud-based computing.

PREQ1 Data Mining Concepts with Relational Databases- Structured Data

Data Mining, the extraction of useful, anonymous data from data in databases. It is also known as KDD (Knowledge Discovery in Databases). The iterative process consists of Data Cleaning, Data Integration, Data Selection, Data Transformation, Data Mining, Data Evaluation, and Knowledge Representation. This will serve as an introduction for Data Mining with Relational Databases.

This is a pre-requisite course for many courses in the Data Science Curriculum. Students are expected to present proficiency level in basic SQL with previous coursework or certifications.

Module II

DS608 Introduction to Algorithms for Data Science

Algorithms in Data Science is a pre-requisite for the Applied Machine Learning Course. Students learn the applications Asymptotic Analysis, Graphs, Divide and Conquer Algorithms, Data structures, Hash tables, Dynamic Programming, Network Flow, NP-completeness, Randomization Algorithms, Heuristics, and Dynamic Programming.

DS609 Data Mining Concepts with Semi-Structured Data/XML

Semi-Structured Data is a form of structured data that does not conform to traditional data models. XML is widely used for Semi-Structured Data. A brief review of Data Mining Concepts would be discussed, which would lead to indexing XML data, transforming relational data to XML data, mining association rules, among other topics.

DS610 Statistical Modeling & Prediction

Students learn to build predictive models with logistic regression, random forests, and Neural Networks. They work on data preparation and transformation, data exploration and running descriptive statistics with data followed by generalized linear and nonlinear models, artificial neural networks, and decision trees, probabilities of profit and loss, model validation, comparison and implementation. The course ends with a case study-based project with SAS and R as the basic programming tools.

Data Visualization:

DS611 Data Visualization and Communication

This course focuses on data representation with Visualizations, Reporting, Communication and Storytelling with industry tools like SAS Visual Analytics and TIBCO spot fire. Students work on importing data, data sources, interpret the chart, graph and table visualizations, edit, modify and create reports, share reports and finally prepare project presentation of Case Studies with Static and Dynamic presentations.

DS612 Information Retrieval, Web and Text Analytics

Students learn about using textual data for data exploration and predictive modeling, cluster, and subgroup data, perform a term-based and string-based search with query filters and create rule-based statistical models for predicting customers sentiments and categorizing documents as per taxonomy using SAS programming. Students are also introduced to the deep knowledge of web analytics and web intelligence, interpreting key web metrics and KPIs for optimizing website design and online marketing.

Prereq (Moon) / Summer Courses

Computing:

PREQ2 Cloud Computing and Big Data

Cloud computing and Big Data work together to store, process, analyze, access, and report information. Analytical techniques can apply on a much grander, faster scale and can be more accessible to users. Topics discussed include Data Elements, Aggregates, Clusters, and Risks of using Big Data with Cloud Computing along with common industry issues in Dimensions of Data Quality such as relevance, accuracy, timeliness, coherence, security, and validity.

This is an optional course in the Data Science Curriculum. Students are expected to present proficiency level with previous coursework or certifications.

Module III

Machine Learning:

DS613 Applied Machine Learning

Applied Machine Learning focuses on writing computer programs that help the computer to present calculated inferences from examples or previous instances rather than a set of rules formulated by syntaxes. This course introduces the theoretical basis of Supervised and Unsupervised Learning with an understanding on conceptualizing a problem, representing data, interpreting results and error handling with error analysis to make judgment on adjusting the data and selecting the algorithms for making the right decisions. The course ends with case study, projects and programming assignments with SAS and R programming, to provide practical exposure.

DS614 Mining Massive Datasets/Data Mining Concepts with Un-Structured Data/Hadoop

Distributed le systems: Hadoop, map-reduce; PageRank, topic-sensitive PageRank, spam detection, hubs-and-authorities; similarity search; shingling, mind hashing, random hyperplanes, locality- sensitive hashing; analysis of social-network graphs; association rules; dimensionality reduction: UV, SVD, and CUR decompositions; algorithms for very- large-scale mining: clustering, nearest-neighbor search, gradient descent, support vector machines, classification, and regression; submodular function optimization.

DS615 Predictive Analytics

This hands-on course will cover concepts of theoryand application of methods and models used for predictive analytics. Topics may include regression analysis, neural networks, random forest, predictive modeling and various statistical regression methods. Gain a fundamental understanding of Predictive Analytics so that students will be able to produce a full data set compatible for building predictive dynamic models using mathematical and statistical concepts.

Module IV: Specialization Track

Track 1: Healthcare

DS617 Clinical Trial Analytics

This course introduces students to clinical trials with a detailed view of all the phases of clinical trial studies, the design of experiments, types of clinical data, data integration and manipulation with a special emphasis on planning statistical analysis tests, preparing tables listing graphical outputs and reports for regulatory submissions using SAS.

DS618 Design and Analysis of Epidemiological Studies

Students with a background in Epidemiology or Public Health and Biostatistics learn about designing epidemiological studies, survey designs, conducting analytical studies with Epi Info to read data and run detailed epidemiological statistics, tables, maps, and graphs. SAS is also used on case study-based projects where students are exposed to real-world design, planning, and analysis of epidemiological studies.

Track 2: Fraud and Security Intelligence

DS619 Fraud and Security Intelligence

Fraud and Security Intelligence discusses the effective methods of identifying fraudulent individuals with data and social network information exploration with SAS Fraud Framework. It also introduces the main concepts, terminology, base functionality related to SAS Anti-Money Laundering, further going into the details of transaction monitoring investigations, conducting in-depth searches of customer activity, adding information to alerts and cases, and viewing reports. Analysts, investigators, and managers benefit greatly with this preparation.

Track 3: Forecasting and Econometrics

DS620 Forecasting and Econometrics

This course is based on the quantitative, statistical, and analytical skills of participants to solve business problems with the basic foundations of building and using econometric models, making strong prediction-based forecasts, and performing econometric analyses with SAS. Students work on proposing solutions by creating and fitting custom forecast models to full-time series data sets, testing and improving forecast efficiency, and doing data updates on large time-series data sets. Students learn about the techniques of business improvement by using social media as a tool for brand management.

Module V

- Assignments
- Quizzes
- Lab hours
- Career sessions

- Soft skills

Module VI: Final Project

Advanced Graduate Certificate in Drug Safety and Pharmacovigilance

The Advanced Graduate Certificate in Drug Safety and Pharmacovigilance program is well-suited for students with a strong background in fields like medicine, dentistry, pharmacy, nursing, biostatistics, computer science, and information technology. There is a growing need for qualified professionals in the pharmaceutical industry, regulatory authorities, and academia.

This program will focus on the regulatory issues and requirements across global government agencies that improve safety by covering topics such as Regulatory Compliance for Drug Safety and Pharmacovigilance, Risk Management, Signal Evaluation, and Reports. Successful navigation of drug safety and pharmacovigilance are keys to product longevity, consumer confidence, and regulatory compliance.

Students will learn about Risk Evaluation and Mitigation Strategy (REMS) and Risk Management Plans (RMPs), and how pharmaceutical companies need to take proactive steps to manage the risk of drugs on the market. They will be trained in signal detection and evaluation in SAS JMP Clinical and Oracle Argus Empirica. Students will also be taught the process of spontaneous Adverse Event (AE) reporting, and other ways of AE reporting in the postmarket area as well as in the clinical trial area.

They will also be taught the World Health Organization's (WHO) pharmacovigilance guidelines, the Food and Drug Administration (FDA) guidelines, the European Union's (EU) good pharmacovigilance guidelines, the Council for International Organizations of Medical Sciences (CIOMS) and the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) regulations for drug safety and pharmacovigilance principles and operations.

CIP Code: 51.9999
Program Hours: 960 Clock Hours
Program Code: AGCDSP
Program Mode: Hybrid

Program Curriculum

Module I

DSP601 Introduction to Drugs, Safety and its Regulations

Drug development is the process of bringing a new pharmaceutical drug to the market once a lead compound has been identified through the process of drug discovery. It includes preclinical research on animals, clinical trials on humans, and the step of obtaining regulatory approval to market the drug. This module will educate students about the basic process of drug development and the regulatory and compliance processes that ensure consumer safety.

DSP602 Organization and Functions of Drug Safety Department

Prescription drugs are crucial for preventing and treating diseases and improving the public's health, but no drug molecule is considered safe unless it proves itself time and again. Hence watchfulnessis mandatory to ensure the safety of the consumers. This process is known as drug safety and pharmacovigilance. The ethical issues of business and medicine have become complex and difficult. The world of big business has now caught up with big medicine. This module will educate students about the business dynamics of the pharmaceutical industry and the ethics, structure, function of the drug safety department, and its training.

DSP603 Regulatory Compliance for Drug Safety and Pharmacovigilance

The discipline of pharmacovigilance and drug safety is highly regulated with ever changing laws and regulations. The World Health Organization (WHO), all national regulators and health agencies and pharmaceutical companies need to communicate with each other to ensure the global safety of every product in the market. This module educates students about the regulatory functions of pharmacovigilance and the manner in which they operationalize.

DSP604 Adverse Events Reporting and Post-Marketing Activities

Pharmacovigilance assesses the safety profile of drugs. It is the science related to the collection, detection, assessment, monitoring, and prevention of the adverse effects of pharmaceutical products. Its main aim in post-marketed drugs is the increase of spontaneous reporting of adverse drug reactions. This module will provide the opportunity to understand the mechanism of the development of adverse events and the vigilance process for the event. This module analyzes the adverse events and explains adverse drug reaction in relation to the drug consumer.

This module further addresses the knowledge and methods of evaluating, reviewing, and analyzing the reports of adverse events.

Module II

DSP605 Introduction to Oracle Argus Safety Application Part I

The course provides training to the students on the features of Argus Safety, its role in fulfilling the pharmaceutical industry's toughest regulatory challenges, and how it supports drug safety business processes from an easy-to-understand user interface. Thorough case processing and discussions will allow students to gain skills regarding handling different types of cases, case processing in the software, and the highest possible quality standards to support accurate detection and analysis of drug safety signals.

BSE616 Basics of Biostatistics and Epidemiology

Students will learn the basic concepts of biostatistics and understand how this knowledge is useful for epidemiologic applications in clinical trials as well as healthcare sectors. Students will learn the basic concepts of epidemiology- the science of diseases in populations; and how biostatistics becomes the language of epidemiology to collect, organize, analyze, interpret the data, and its proper use for healthcare and clinical trial forecasting and regulatory issues.

LTR618 Literature Review

This course is designed to train students in the conduct of a systematic literature review and develop the skills to conduct a review in order to develop competencies in reading and writing scholarly literature, such as research proposals, dissertations, and research papers. The course will alsoexpose students to important standards in the arena of literature reviews.

PTM617 Project Management

This course will introduce the generic concepts and principles of project management, strategic planning, and leadership. The course will cover the full life cycle of a project including project initiation, planning, execution, control, and closeout; and define the role of a project manager in developing and maintaining the timeline, budgets, and quality of a project. Students will be exposed to the principles of project management processes and they will also learn about the tools and techniques of scope, time, cost, quality, risk, human resource procurement, and stakeholder's management.

Module III

DSP607 Risk Management, Signal Evaluation, and Reports

One of the most important and challenging problems in pharmacovigilance is that of the determination of causality. Causality may be determined at the individual case level or in aggregate data. This module will educate students about the process of coding, causality assessment, signal evaluation, quality analysis, and also about reporting to regulatory authorities.

DSP608 Introduction to Drug Safety Physician Functions: MedDRA, ADR, Narrative Writing Part I

The pharmacovigilance function is centered on assigning causality to an adverse event through medical review. This module will educate students about the process of coding with MedDRA and medical narrative writing in general as well as the ADR of various systems.

DSP609 Drug Safety Physician Functions in Pharmacovigilance: Narrative Writing Part II

Causality evaluation starts with narrative writing that involves expressing the messages clearly and effectively, while collating the relevant information from various sources and using medical expertise to scrutinize the information. A narrative tells the complete story chronologically and holds together medically. Identifying and relating the relevant medical history or laboratory result to the event of interest can be challenging. This module will educate students about the process of medical narrative writing in the ADR of various systems and will make them aware about recent advances in the area of adverse drug reactions in different systems.

DSP610 Oracle Argus Safety Application Part II

Students will learn about the configuration of products, and how licenses are authorized in different countries. Products and licenses act as the main pillars of Argus Safety and help in the scheduling of reports and in fulfilling regulatory obligations. The course will also address the preparation of periodic reports and extraction of case listings, which are helpful in the critical analysis of the risk benefit evaluation of drugs**.**

Module IV

DSP614 Recent Advances: REMS, Action and Drug Withdrawals

Risk Evaluation and Mitigation Strategies (REMS) is a safety strategy to manage a known or potentially serious risk associated with a drug, and to enable pharmaceutical companies to have continued risk evaluation of such medicines and manage their safe use. This module provides an

understanding of the implementation of the regulatory and voluntary proactive actions required to be implemented by pharmaceutical companies to mitigate safety issues that arise out of reports and are needed for the continued safety of the drug to remain in the market.

DSP611 Signal Detection Using Empirica

The signal detection course shall cover a myriad of topics from detecting signals through validation and confirmation, analysis, prioritization, and assessment to recommending action. The course will also teach students how to track steps taken and make recommendations.

DSP613 Analytics in Pharmacovigilance Argus Insight

Argus Insight, formerly called Power Reports, is a highly optimized reporting module that complements Argus Safety. The Argus Insight Extract Transform and Load (ETL) engine extracts data from the Argus Safety database and populates a data warehouse in a format that allows efficient querying. The query, drill-down, and output components of Argus Insight allow it to analyze safety, workflow, or product data from all angles and produce reports that provide immediate business impact and maximum efficiency in decision-making.

Argus Analytics

With the Oracle Argus Analytics software tool, pharmaceutical companies and contract research organizations (CRO) can keep tabs on how efficiently case processing is performed, their overall safety compliance with regulatory authorities, and a day-to-day assessment of the drug safety personnel required to maintain a smooth operation of the drug safety department.

Oracle Argus Analytics also functions as a decision support system to monitor process bottlenecks and compliance deviations. Oracle Business Intelligence Enterprise Edition (OBIEE) can be integrated with the existing Argus Safety application. The interactive OBIEE dashboard will provide solutions to business questions and present data in charts, pivot tables, and reports.

Module V: Internship program in Drug Safety/Pharmacovigilance

Target Audience:

Health profession students and practitioners who have completed a training program in Drug Safety and Pharmacovigilance.

Requirements and Duration:

Participants must have access to Oracle Argus Safety database

Total length of the program is 12 weeks.

The program will run every Saturday from 10:00 am to 3:30 pm.

The 10 Objectives:

The goal of the Internship Program in Drug Safety and Pharmacovigilance is to provide a comprehensive practical experience in processing ICSRs from book-in to distribution.

1. Triage cases based on seriousness and regulatory time frame.
2. Identify case-relevant data to be extracted from the source document.
3. Accurately enter the data in Argus Safety.
4. Product research and coding.
5. Accurately MedDRA code medical history, past drugs, indications, and AEs.
6. Assess causality and listedness.
7. Write a comprehensive narrative in chronological order.
8. Upgrade cases to serious based on source, labs, and medical judgement.
9. Contact log case processing decisions.
10. Route case to next workflow level.

Amazon Web Services

The Amazon Web Services (AWS) training program will provide students with the basic concepts of the cloud-computing services that make up the cloud-computing platform offered by Amazon.com. AWS is a type of site. It is a subsidiary of Amazon.com that provides on-demand cloud-computing platforms to individuals, companies, and governments on a paid subscription basis.

Students will cover languages such as SQL; Python; and Amazon Electric Compute Cloud (EC2), which forms a central part of Amazon.com's cloud-computing platform by allowing users to rent virtual computers on which to run their own computer applications. They will also learn about Amazon S3 or Amazon Simple Storage Service, an online file storage web service that provides object storage through web services interfaces such as REST, SOAP, and BitTorrent.

CIP Code: 11.0103
Program Hours: 250 Clock Hours
Program Code: ?
Program Mode: Hybrid

Program Curriculum

Module 1: Introduction

1. Introduction to basic SQL, SQL constructs
2. Introduction to Python scripting – data manipulations, string operations
3. Introduction to cloud computing and AWS
4. Overview of services – storage, processing, DB, and so on
5. Understanding the difference between PaaS (Platform as a Service) and IaaS (Infrastructure as a Service)

Module 2: Specific AWS Services

1. VPC, S3 (Object storage basics, EBS, EFS, IAM)
2. EC2, EMR, Lambda (using Python)
3. Glue
4. Kinesis
5. Data Processing

Module 3: Loading and Querying

1. Aurora DB (MySQL or Postgres) – Use SQL constructs studied in Module 1
2. Basics of DynamoDB – How to load, how to query
3. Security and roles – Basics on the databases
4. Querying on top of data in S3 – Athena, Hive on S3
5. DMS Services

Module 4: Data Warehouse (DWH) & Redshift Training

1. Basics of DWH modeling – Star schema, Dimensional Modeling
2. DWH appliance concepts and DWaaS (Data Warehouse as a Service)
3. Redshift Features – Loading data into Redshift, SQL hands-on with data on Redshift, Spectrum concepts, Clustering concepts, the Sort by and Distribute by, Vacuum
4. Hands-on in Redshift – Be able to orchestrate Redshift SQL via Python; Process data in S3 with combination of Python & Redshift SQL

Module 5: AI (Artificial Intelligence) & ML (Programming Language)

1. AI and ML Basics
2. AWS AI

3. AWS Machine Learning
4. AWS Chatbots

Big Data Analytics

The Big Data Analytics program will teach students about the skills needed for big data engineering and data analytics by introducing them to the big data engineering ecosystem. Students will learn about the parallel computing ecosystems of Hadoop and those of streaming systems like Spark. They will also study analytical and applied methods like data mining, machine learning, and data visualization.

A big data analyst must possess skill sets that enable him or her to support any organization and its management with clear and insightful analyses on the data at hand. These skills include data mining (including data auditing, aggregation, validation, and reconciliation), advanced modeling techniques, testing and creating, and explaining results in clear and concise reports.

In addition to Hadoop and Spark, students will learn how to use the best tools in the industry like Java, Python, R, and Map Reduce. Students with backgrounds ranging from mathematics, statistics, computer science to business administration, economics, or finance will benefit from this program. Students will learn how to communicate complex findings and ideas in plain language, and be able to work in teams toward a shared goal.

CIP Code: 52.1301
Program Hours: 300 Clock Hours
Program Code:
Program Mode: Hybrid

Program Curriculum

Module 1: Hive

This module covers Hive architecture and configuration fundamentals including partitioning, bucketing, configuration settings for high performance queries, user-defined functions, user-defined tabular functions, and user-defined aggregate functions with the purpose of providing base and hands-on exposure to customize Hive query evaluation and manipulation functionalities. Learners will be exposed to different functions including build in, constructor,

and Boolean. ANSI Standards for query development, key functions, and key constructs will also be covered.

Module 2: HBase

This module covers the constructs and functionalities of HBase by focusing on the building blocks of Hbase Column family; HBase data model; versioned data in HBase; aspects of the HBase Language Manual; Hbase table design; Row Key formats; and columnar functionalities including models and families, wide column designs, DDL, DML, and other commands. Students will also learn about key functions including KeyOnlyFilter, ColumnPrefixFilter, MultipleColumnPrefixFilter, and InclusiveStopFilter.

Module 3: Spark

Students will cover the Spark architectural ecosystem and components including how Spark Clusters and files work, and a comparative study of Spark and Hadoop clusters. The module will also cover Spark RDD fundamentals and working components including creating RDDs from data files, RDD transformations, structure manipulation, RDD APIs, and interactive queries. Students will also learn about Spark batch and streaming designs, micro batching concepts, and windows functions with programming interfaces like Scala and Python.

Module 4: ETL, PIG

This module covers the concepts and functionalities of batch and real time ETL designs including how to implement them. Design considerations and patterns for ingestion, extraction, and transformation aspects; ETL pipeline performance tuning from the perspective of Hive queries, Map Reduce, Pig Scripts, HBase query and Spark jobs will also be covered.

Module 5: Data Visualization with Tableau

This module focuses on data representation with visualizations, reporting, communication, and storytelling with industry tools like Tableau. Students work on importing data; interpreting the chart, graph, and table visualizations; and editing, modifying, and creating reports. Data visualization with Tableau makes insights come alive with impact and communicates complex ideas simply. Expressive visualization enables you to get beyond static charts to create multi-faceted views of data and explore every dimension.

Module 6: Python Including Shell Scripting

This module covers shell scripting, Python, programming, and applied machine learning methodologies. Students will learn about several domains including Bayesian learning methods, program (or project) evaluation and review technique (PERT), data collection and preparation, linear classification, decision trees and random forests, regression, non-linear classification with neural networks and kernels, model validation, feature selection, cluster analysis, data structure, and text mining. Case studies will also be covered in different domains.

Big Data Engineering

Data engineers build and work on massive reservoirs of big data. They develop, construct, test, and maintain architectures such as databases and large-scale data processing systems. Once continuous pipelines are installed to and from these huge "pools" of filtered information, data scientists can pull relevant data sets for their analyses. From the analysis of this "big data," businesses can learn key insights about their customers to make informed business decisions. Scientists can discover previously unknown patterns hidden deep inside the mountains of data.

This program will teach students about the key techniques used to design and build big data systems and gain familiarity with data acquisition, data cleansing, database management, and data engineering. Students will work on real-world applications through case studies; projects; and a capstone experience during which students will obtain, condition, explore, model, and interpret a big data set. Students will work with the best tools including Hadoop, Pig, Hive, HBase, Oracle, and MongoDB.

Graduates of the program will be able to design, construct, install, test, and maintain highly scalable data management systems; ensure that systems meet business requirements and industry practices; build high-performance algorithms, prototypes, predictive models, and proof of concepts; collaborate with data architects, modelers, and IT team members on project goals; employ a variety of languages and tools to marry systems together; and install and update disaster recovery procedures.

CIP Code: 11.0802
Program Hours: 300 Clock Hours
Program Code: BSIDE
Program Mode: Hybrid

Program Curriculum

BSIDE300 Java Foundation

Java is a general-purpose computer programming language that is concurrent, class-based, object-oriented, and specifically designed to have as few implementation dependencies as possible. It is intended to let application developers "write once, run anywhere" (WORA), meaning that compiled Java code can run on all platforms that support Java without the need for recompilation. Java applications are typically compiled to bytecode that can run on any Java virtual machine (JVM) regardless of computer architecture. By and large, Java has been the most popular programming languages in use. This course is structured in three stages – the fundamentals, web application and database application.

BSIDE301 Hadoop

Hadoop is an open-source software framework used for distributed storage and processing of dataset of big data using the MapReduce programming model. It consists of computer clusters built from commodity hardware. All the modules in Hadoop are designed with a fundamental assumption that hardware failures are common occurrences and should be automatically handled by the framework.

BSIDE302 Hive

Hive is a data warehousing infrastructure for Hadoop. The primary responsibility is to provide data summarization, query and analysis. It supports analysis of large datasets stored in Hadoop Distribution File System (HDFS) as well as on Amazon S3 filesystem. Hive allows SQL developers to write Hive Query Language (HQL) statements that are similar to standard SQL statements. Hive gives the functionalities of SQL like data warehousing.

BSIDE303 HBase

HBase is a column-oriented database management system that runs on top of HDFS which is well suited for sparse datasets, common in big data use cases. HBase is non-relational distributed database similar to BigTable (from Google) like properties with in-memory operations. HBase applications are written in Java much like a typical MaReduce application. An HBase system comprises of a set of tables. Each table contains rows and columns, much like a traditional database.

BSIDE304 Pig

Pig is a programming language designed to handle any kind of data that was initially developed by Yahoo. Pig consists of two parts: the first is the language itself, which is called Pig Latin and

the second part is the runtime environment where Pig Latin programs are executed. Pig is used to execute MapReduce jobs in Hadoop and it has similar functionalities as that of SQL.

BSIDE402 ETL Development

The Extract-Transform-Load (ETL) system is the foundation of the data warehouse. A properly designed ETL system extracts data from the source systems, enforces data quality and consistency standards, conforms data so that separate sources can be used together, and finally delivers data in a presentation-ready format so that application developers can build applications and end users can make decisions. The ETL system makes or breaks the data warehouse. Building an ETL system is more like a backroom activity that is not very visible to the end users.

CAP613 Capstone Project

Capstone project is an extension of Specialization track. Students select a Specialization track followed by related coursework ending with Project presentation relevant to applications of Big Data in Healthcare, Security Intelligence or Forecasting and Econometrics or any area of interest. They may also get access to online websites that provide Big Data datasets.

Biostatistics

Using the tools of statistics, biostatisticians help answer pressing research questions in medicine, biology, and public health such as whether a new drug works, what causes cancer and other diseases, and how long a person with a certain illness is likely to survive. Biostatisticians are not mere number crunchers. They use their quantitative skills to work with experts in other fields, from biologists and cancer specialists to surgeons and geneticists. They play pivotal roles in designing studies to ensure that enough data and the right kind of information are collected. Then they analyze, evaluate, and interpret the results accounting for variables, biases, and missing data along the way.

Students will learn the basics of statistics and apply statistical knowledge to compare samples and interpret statistical significance. They will prepare mathematical and predictive models that could facilitate solutions toward healthcare. Students will learn how to take a leadership role in the design and implementation of a health science project, and assume responsibility for the design and implementation of analyses for health science investigations. They will also assist with the design and implementation of data management systems for large health science studies.

The program will equip students with a broad knowledge and understanding of statistical theory and practice as applicable in the health sciences. They will learn how to function as a collaborator on a research team, prepare reports and publications resulting from health science studies, and serve as an advocate for good statistical design in health science investigations.

CIP Code: 26.1102
Program Hours: 300 Clock Hours
Program Code: ?
Program Mode: Hybrid

Program Curriculum

Fundamental Statistics

Probability & Statistics

Our focus is to get to the basis firsts with concepts and theories in probability with special focus to Bayesian approach. The other part of the course focusses on Inferential statistics where we learn to infer from the sample data what the population might be. We use inferential statistics to make judgments of the probability that an observed difference between groups is a dependable one or one that might have happened by chance in this study. Thus, we use inferential statistics to make inferences from our data to more general conditions; we use descriptive statistics simply to describe what's going on in our data. This course covers the role of statistics in healthcare with examples covering the topics on probability and Inferential statistics.

Exploratory Data Analysis

John Tukey is considered the father of Exploratory data analysis. exploratory data analysis (EDA) is an approach to analyzing data sets to summarize their main characteristics, often with visual methods. A statistical model can be used or not, but primarily EDA is for seeing what the data can tell us beyond the formal modeling or hypothesis testing task. Exploratory data analysis was promoted by John Tukey to encourage statisticians to explore the data, and possibly formulate hypotheses that could lead to new data collection and experiments.

EDA is different from initial data analysis (IDA), which focuses more narrowly on checking assumptions required for model fitting and hypothesis testing, and handling missing values and making transformations of variables as needed. In this course, we will be using R to make some meaningful plots and summaries using R.

Regression Analysis

In statistical modeling, regression analysis is a set of statistical processes for estimating the relationships among variables. It includes many techniques for modeling and analyzing several variables, when the focus is on the relationship between a dependent variable and one or more independent variables (or 'predictors'). More specifically, regression analysis helps one understand how the typical value of the dependent variable (or 'criterion variable') changes when any one of the independent variables is varied, while the other independent variables are held fixed.

In general regression analysis is a way of mathematically sorting out which of those variables does indeed have an impact. It answers the questions: Which factors matter most? Which can we ignore? How do those factors interact with each other? And, perhaps most importantly, how certain are we about all of these factors? Regression analysis is widely used for prediction and forecasting, where its use has substantial overlap with the field of machine learning. Regression analysis is also used to understand which among the independent variables are related to the dependent variable, and to explore the forms of these relationships.

Data Mining

Data mining is the computing process of discovering patterns in large data sets involving methods at the intersection of machine learning, statistics, and database systems. It is an interdisciplinary subfield of computer science with application of statistical techniques and models and artificial intelligence. Aside from the raw analysis step, it involves database and data management aspects, data pre-processing, model and inference considerations, interestingness metrics, complexity considerations, post-processing of discovered structures, visualization. The main objective of this course would be to understand the process of finding anomalies, patterns and correlations within large datasets to predict the outcomes. We will use different techniques for different analytics outcome i.e., descriptive, diagnostic, discovery, predictive and prescriptive.

Time Series Analysis

A time series is a series of data points indexed (or listed or graphed) in time order. Most commonly, a time series is a sequence taken at successive equally spaced points in time therefore it is a sequence of discrete-time data. Examples of time series are heights of ocean tides, counts of sunspots, and the daily closing value of the Dow Jones Industrial Average.

Time series are very frequently plotted via line charts. Time series are used in statistics, signal processing, pattern recognition, econometrics, mathematical finance, weather forecasting, intelligent transport and trajectory forecasting, container shipping freight rate forecasting,

earthquake prediction, electroencephalography, control engineering, astronomy, communications engineering, and largely in any domain of applied science and engineering which involves temporal measurements. Time series forecasting is the use of a model to predict future values based on previously observed values. While regression analysis is often employed in such a way as to test theories that the current values of one or more independent time series affect the current value of another time series, this type of analysis of time series is not called "time series analysis", which focuses on comparing values of a single time series or multiple dependent time series at different points in time. Interrupted time series analysis is the analysis of interventions on a single time series.

Core (Bio)Statistics

Epidemiology

Epidemiology is the study and analysis of the patterns, causes, and effects of health and disease conditions in defined populations. It is the cornerstone of public health, and shapes policy decisions and evidence-based practice by identifying risk factors for disease and targets for preventive healthcare. Epidemiologists help with study design, collection, and statistical analysis of data, amend interpretation and dissemination of results. Epidemiology has helped develop methodology used in clinical research, public health studies, and, to a lesser extent, basic research in the biological sciences.
This course introduces the basic concepts of epidemiology and biostatistics as applied to public health problems. Emphasis is placed on the principles and methods of epidemiologic investigation, appropriate summaries and displays of data, and the use of classical statistical approaches to describe the health of populations, various epidemiologic study designs for investigating associations between risk factors and disease outcomes, culminating with criteria for causal inferences. The influence of epidemiology and biostatistics on legal and ethical issues are also discussed. This program will help to apply principles of epidemiology and biostatistics to the prevention of disease and the improvement of health.

Non-Parametric Statistics

Nonparametric statistics refer to a statistical method wherein the data is not required to fit a normal distribution. Nonparametric statistics uses data that is often ordinal, meaning it does not rely on numbers, but rather a ranking or order of sorts. For example, a survey conveying consumer preferences ranging from like to dislike would be considered ordinal data. Nonparametric statistics have gained appreciation due to their ease of use. As the need for parameters is relieved, the data becomes more applicable to a larger variety of tests. This type of statistics can be used without the mean, sample size, standard deviation, or the estimation of any other related parameters when none of that information is available.

Design of Experiments

Design of experiments (DOE) is a systematic method to determine the relationship between factors affecting a process and the output of that process. In other words, it is used to find cause-and-effect relationships. This information is needed to manage process inputs in order to optimize the output.

An understanding of DOE first requires knowledge of some statistical tools and experimentation concepts. Although a DOE can be analyzed in many software programs, it is important for practitioners to understand basic DOE concepts for proper application.

Survival Analysis

Survival analysis is used to analyze data in which the time until the event is of interest. The response is often referred to as a failure time, survival time, or event time. Some of the examples that we would be interested in survival analysis are Time until tumor recurrence, Time until cardiovascular death after some treatment intervention, Time until AIDS for HIV patients, Time until a machine part fails.

Capstone Project

Capstone project is an extension of Specialization track. Students select a Specialization track followed by related coursework ending with Project presentation relevant to applications of genetics, clinical trials, genomics, disease surveillance, epidemiology, and so on.

SAS Clinical

Clinical Trial Data Structures

- Identify the classes of clinical trials data (demographic, lab, baseline, concomitant medication, etc.)
- Identify key CDISC principals and terms
- Describe the structure and purpose of the CDISC SDTM data model
- Describe the structure and purpose of the CDISC ADaM data model
- Describe the contents and purpose of define.xml

Import and Export Clinical Trials Data

- Combine SAS data sets
- Efficiently import and subset SAS data sets

- Access data in an Excel workbook (LIBNAME and PROC IMPORT/EXPORT)
- Create temporary and permanent SAS data sets
- Apply regulatory requirements to exported SAS data sets (SAS V5 requirements)

Manage Clinical Trials Data

- Investigate SAS data libraries using base SAS utility procedures (PRINT, CONTENTS, FREQ)
- Access DICTIONARY Tables using the SQL procedure
- Sort observations in a SAS data set
- Create and modify variable attributes using options and statements in the DATA step
- Examine and explore clinical trials input data (find outliers, missing vs. zero values, etc.)

Transform Clinical Trials Data

- Process data using DO LOOPS
- Process data using SAS arrays
- Retain variables across observations
- Use assignment statements in the DATA step
- Apply categorization and windowing techniques to clinical trials data
- Use SAS functions to convert character data to numeric and vice versa
- Use SAS functions to manipulate character data, numeric data, and SAS date values
- Transpose SAS data sets
- Apply 'observation carry forward' techniques to clinical trials data (LOCF, BOCF, WOCF)
- Calculate 'change from baseline' results
- Obtain counts of events in clinical trials

Apply Statistical Procedures for Clinical Trials

- Use SAS procedures to obtain descriptive statistics for clinical trials data (FREQ, UNIVARIATE, MEANS, SUMMARY)
- Use PROC FREQ to obtain p-values for categorical data (2x2 and NxP test for association)
- Use PROC T-TEST to obtain p-values for continuous data (one-sample, paired and two-sample t-tests)
- Create output data sets from statistical procedures

Macro Programming for Clinical Trials

- Create and use user-defined and automatic macro variables
- Automate programs by defining and calling macros
- Use system options to debug macros and display values of macro variables in the SAS log (MPRINT, SYMBOLGEN, MLOGIC, MACROGEN)

Report Clinical Trials Results

- Use PROC REPORT to produce tables and listings for clinical trials reports
- Use ODS and global statements to produce and augment clinical trials reports

Validate Clinical Trial Data Reporting

- Explain the principles of programming validation in the clinical trial industry
- Utilize the log file to validate clinical trial data reporting
- Use programming techniques to validate clinical trial data reporting (PROC COMPARE, MSGLEVEL)
- Identify and resolve data, syntax, and logic errors

Clinical Data Science

Clinical Data Science is a rapidly growing industry that requires trained professionals in the cross functional domain of healthcare, pharmaceutical research, and information technology (IT). Drug discovery and its further development through clinical trials generates enormous data that needs clinical data scientists in increasingly large numbers to support the pharmaceutical activities of research, development, and marketing of drugs.

The program is designed to provide extensive training in the niche domain of clinical research, and serve as an introduction to statistics with industry languages such as R, SAS, Structured Query Language (SQL), Hadoop, Spark, and Tableau. Students will be trained on all aspects of clinical research with a special focus on clinical trial management processes and documentation.

Students will learn how to use the Clinical Data Interchange Standards Consortium's (CDISC) standard definitions for the pharmaceutical industry. CDISC is a global nonprofit organization that develops data standards to streamline clinical research and enable connections to healthcare. Students will be trained on how to submit data to the Food and Drug Administration (FDA) using the Study Data Tabulation Model (SDTM) and the Analysis Data Model (ADaM) table structures and content.

CIP Code: 11.0401
Program Hours: 210 Clock Hours
Program Code:
Program Mode: Hybrid

Program Curriculum

Module 1

Statistics with R

This course introduces the theoretical concepts of Statistics with programming tools for Clinical Data science. Theoretical Concepts of Data Exploration, Comparison, Theory of Probability, Data distributions, Sample size and Estimation, Univariate, Bivariate and Multivariate analysis, Tests of Hypothesis, Inferences, Contingency tables are introduced with statistical problem solving.

Tools
Statistics and R

Project

Students will have hands-on experience with real time project on statistics concepts.

Module 2

Data Visualization with Tableau

This course focuses on data representation with visualizations, reporting, communication and storytelling with industry tools like Tableau, and other industry tools such as SAS Analytics. Students work on importing data, interpreting the chart, graph and table visualizations, editing, modifying and creating reports. Students will also share reports and finally prepare a project presentation of case studies with static and dynamic results.

Data visualization with Tableau makes insights come alive with impact and communicates complex ideas simply. Expressive visualization enables you to get beyond static charts to create multi-faceted views of data and explore every dimension.

Tools
Tableau, SAS (Statistical Analytic system).

Project
Students will have hands-on experience with real time project on tableau, SAS.

Module 3

SQL, Spark and Hadoop

This course starts with concepts in Structured Query Language. The course describes the specific structure of databases in their organization, and content. It then proceeds to an in-depth understanding of accessing and using data with Structured Query Language, data warehousing, and requirement gathering. With Hadoop students learn fundamental components such as MapReduce, HDFS, and YARN Explore MapReduce in depth, the Hadoop Distributed Filesystem, Hadoop I/O, developing a MapReduce Application, Setting Up the Development Environment, How MapReduce Works, MapReduce Types and Format.

MapReduce Features, Hadoop Operations, Setting Up a Hadoop Cluster, Administering Hadoop, Related Projects, Pig, Hive, Crunch, Spark, HBase and Zookeeper.

Tools
Hadoop, Spark, SQL
Project
Students will have hands-on experience with real time project on Hadoop, Spark, SQL.

Module 4

Clinical Research and Clinical Data Management

This course introduces the concepts of Clinical research processes including good clinical practices, roles and responsibilities of a clinical research associate, understanding IRB's, informed consent process, case report forms, and regulatory compliance. Also, drug inventory management, sponsor/FDA Audit preparedness, drug returns, and site closeout responsibilities would be covered. On the Data Management side, students will develop an advanced understanding of the process, systems, techniques and documentation using sample study documentation.

Tools
Inform consent process, Documentation process.

Project
Students will have hands-on experience with real time case scenarios

Module 5

SAS Clinical and SAS with CDISC

This course will cover essential statistical and clinical research concepts, base SAS programming and a comprehensive introduction to working with SAS Clinical data. Some of the topics covered

would be the Statistical analysis plan, and the SAS programming environment and language. SAS Clinical demonstrates how to create and manipulate data sets, import and export and manage clinical trial data as well.

The program introduces the essentials for using SAS Clinical with industry CDISC (SDTM and ADAM) standards to register source and target tables and to create and manage jobs that transform source tables and load them into target data structures. SAS Clinical Data Integration supplies pre-defined CDISC standard definitions for SDTM and ADaM table structures and content and this program shows how to leverage those standard definitions to create jobs that transform source data from clinical studies to load those SDTM and ADaM standard structures, to validate the structure and content of those data structures based on the standards, and to generate CDISC standard define.xml files describing the SDTM domains and ADaM datasets that are part of clinical submissions.

Tools

SAS 9.4

Project

Students will have hands-on experience with real time project on Statistical Analytic System (SAS)

Module 6

3 Months Internship

- 3 Major Projects with Cytel
  - Theoretical concepts to get reinforced by practical exposure
  - Industry related case studies.
- Exclusive support of experienced project coordinators and mentors having global exposure of clinical programming.
- Online discussion forum for each project.
- Query logs to be maintained by Monitors.
- Regular weekly meeting and email support.

1st Project

Analysis Dataset Development

In this project students need to create Analysis dataset for Laboratory data. They need to derive the required variables, create flags for minimum and maximum lab values.

2nd Project

QC of SDTM Dataset Development

In this project students need to generate Demography and Disposition dataset as per SDTM standards by using given raw datasets. By comparing these datasets with developer's data sets they need to check that, if data are mapped correctly as per SDTM standards.

3rd Project

QC of AE and DM Tables

In this project students need to generate summary report for Demography and Adverse events data. They need to produce summary statistics for continuous variables and frequency and percentage for categorical variables of Demography data as per mock shell. They also need to generate summary table for Treatment emergent adverse events as per given mock shell.

Clinical Research and Drug Safety Data Analytics

Sollers provides a unique opportunity for futuristic careers in Clinical Research and Drug Safety Data Analytics. Students who register for this program will have the opportunity to follow the drug development paradigm with various types of data and its varied analysis processes.

Part 1 of the program starts with a clinical trial management module that teaches students about the drug development process through experiments that generate efficacy and safety related data from various phases of clinical trials. Students will complete an internship program that will train them further for the next stage of drug development using various industry tools and systems.

Part 2 covers the drug safety and pharmacovigilance component of the program where students learn to continue to follow the drug in the open market. Among other topics, students learn about postmarketing safety, risk evaluation and mitigation strategy, and risk-benefit analysis of marketed products for safety evaluation and regulatory compliance.

Part 3 focuses on clinical data science and highlights the intensive study of the software and application tools that students will practice on in order to understand how the data generated from clinical trials, the open market, and various phenotypes gets onto a standardized and harmonized SDTM (Study Data Tabulation Model) and ADaM (Analysis Data Model) modules for submission to regulatory authorities. The application of analytics is to learn how the clinical trial

data and drug safety data are planned, validated, captured, monitored, audited, and stored into various clinical data bases, and finally analyzed and submitted.

CIP Code: 51.1005
Program Hours: 900 Clock Hours
Program Code:
Program Mode: Hybrid

Program Curriculum

PART 1

1. **Study Start up**
    - Module 1
        - 1Phases of Clinical Trials
        - ICH GCP Guidelines
        - Study Feasibility and Site Selection
    - Module 2
        - IRB/IEC
        - Budgets
        - Contracts
    - Module 3
        - Essential Documents (Prior to Start of Study)
        - Financial Disclosure Form
        - Clinical Trial Protocol
    - Module 4
        - Investigator Brochure
        - Informed Consent Process
        - Monitoring – General Introduction to all the Types of Visits
2. **Study Conduct**
    - Module 5
        - Site Monitoring Visits
        - Randomization and Blinding
        - Recruitment/Retention/Compliance
    - Module 6

- AE/SAE Reporting Guidelines
- Drug Advertisement
- HIPAA Regulations

- Module 7
  - Medical Devices
  - Fraud/Misconduct, Potential Liability

- Module 8
  - FDA Inspection
  - Essential Documents (During Study Conduct)

3. Study Close-Out

- Module 9
  - Site Close-Out Visit (On-Site/Remote Activities)
  - Site Performance

- Module 10
  - IND/NDA Application Process
  - e CTD (Common Technical Document)

- Module 11
  - Essential Documents (After Study Close-Out)
  - Risk-Based Monitoring

- Module 12
  - Evidence Based Medicine
  - Personalized Medicine
  - Big Data

20-Week Internship Program

Week 1

- Introduction to Clinical Trials
- Phases of the Clinical Trials
- ICH/GCP (E6) R2 Guidelines
- Study Feasibility Questionnaire
- Introduction to CTMS system

Week 2

- Training for CTMS system
- Setting up Sites in CTMS system
- Setting Site staff in CTMS system
- FDA Form 1572

Week 3

- Qualification Visit Confirmation Letter
- Raise Issues in CTMS system
- Generate Qualification report in CTMS system
- Generate Qualification Follow-up Letter

Week 4

- Site Initiation Visit Confirmation Letter
- Raise Issues in CTMS system
- Generate Site Initiation report in CTMS system
- Generate Site Initiation Visit Follow-Up Letter

Week 5

- IRB Approval Letter Initial and Continuing Review
- IRB approval Tracking Tool
- Budget Template
- Contract Template
- Introduction to TMF

Week 6

- Training Modules in TMF
- Upload Essential Documents
- Sample Financial Disclosure Form
- Clinical Trial Protocol Template
- Protocol Amendment Tracking Tool

Week 7

- IB Sample Template
- Training Modules in TMF
- Informed Consent Form Template
- Informed Consent Form Tracking Tool
- Introduction to Monitoring in CTMS system

Week 8

- Introduction to EDC system
- Data Entry into eCRF
- Source Data Verification
- Raise Queries
- Investigational Product Accountability using IPAL

Week 9

- Monitoring Visit Confirmation Letter
- Raise Issues in CTMS system
- Generate Monitoring Visit Report
- Generate Monitoring Visit Follow-Up Letter

Week 10

- Remote Site Management using CTMS system
- Mock Tele-Conference with Site
- Issue Resolution
- Generate Remote Site Monitoring Visit Report

Week 11

- Introduction to Global Medical Safety
- AE Data Entry in EDC system
- SAE Data Entry in EDC system
- Sample SAE Report
- SAE Reconciliation

Week 12

- Training Modules in TMF
- TMF Metrics
- TMF Placeholders
- Upload Essential Documents into TMF

Week 13

- Training Modules in CTMS system
- Update Site Staff
- Regulatory Document Tracking
- Track IRB Approvals
- Study Timelines

Week 14

- Introduction to FDA Inspection
- FDA.gov Resource
- Mock FDA Inspection
- Inspection Readiness Tracking using TMF

Week 15

- Introduction to HIPAA
- Sample HIPAA Compliance Form
- Sample Case Studies for Fraud, Misconduct, and Potential Liability

Week 16

- Generate Site Closeout Confirmation Letter
- IP Accountability and Reconciliation
- Sample IP Accountability Log
- Temperature Excursion Log
- Drug Destruction Form
- Generate Site Closeout report using CTMS system
- Generate Site Closeout Follow-Up Letter

Week 17

- Sample IND application
- Sample NDA application
- Upload Essential Documents using TMF
- Site Master File-TMF Reconciliation

Week 18

- Site Closeout activities in CTMS system including Site Closeout confirmation letter, Closeout Visit Report, Closeout follow-up letter
- Site Closeout activities in TMF
- Site Closeout activities in EDC system

Week 19

- Mock Site Qualification Visit in CTMS system
- Mock Site Initiation Visit in CTMS in CTMS system

Week 20

- Mock Site Monitoring Visit in CTMS System

- Mock Site Closeout Visit in CTMS system

PART 2

Introduction to Drugs, Safety and its Regulations

Drug development is the process of bringing a new pharmaceutical drug to the market once a lead compound has been identified through the process of drug discovery. It includes preclinical research on animals, clinical trials on humans, and the step of obtaining regulatory approval to market the drug. This module will educate students about the basic process of drug development and the regulatory and compliance processes that ensure consumer safety.

1. Drug Development Process
2. Ethics of Human Subject Protection
3. Good Clinical Practice in Clinical Trials

Organization and Functions of Drug Safety Department

The ethical issues of business and medicine have become complex and difficult. The world of big business has now caught up with big medicine. This module will educate students about the business dynamics of the pharmaceutical industry and the ethics, structure, function of the drug safety department, and its training.

1. Ethics, Honesty, and Business Dynamics at Play
2. Understand Drug Safety Department
3. Training in Drug Safety Career for New Hire

Regulatory Compliance for Drug Safety and Pharmacovigilance

The discipline of pharmacovigilance and drug safety is highly regulated with ever changing laws and regulations. The World Health Organization (WHO), all national regulators and health agencies and pharmaceutical companies need to communicate with each other to ensure the global safety of every product in the market. This module educates students about the regulatory functions of pharmacovigilance and the manner in which they operate.

1. Pharmacovigilance and Regulatory Needs
2. U.S. FDA: Regulatory Scenario
3. Europe, ICH, CIOMS, and International Regulatory Scenario

Adverse Events Reporting and Post-Marketing Activities

Pharmacovigilance assesses the safety profile of drugs. It is the science related to the collection, detection, assessment, monitoring, and prevention of the adverse effects of pharmaceutical products. This module will provide the opportunity to understand the mechanism of the development of adverse events and the vigilance process for the event. This module analyzes the adverse events and explains adverse drug reaction in relation to the drug consumer. This module further addresses the knowledge and methods of evaluating, reviewing, and analyzing the reports of adverse events.

1. Adverse Events Reporting and Post-Marketing Activities
2. Adverse Event Evaluation Seriousness, Expectedness, and Causality
3. Understand the Role of MedWatch Form and Importance of Patient-Reporter Details in ICSR
4. Importance of Event Details in ICSR and Importance of Product Details in ICSR
5. Dynamics of AE Reporting
6. Need to Follow-up and Completion of Reports and Importance and Significance of Voluntary Reports

Introduction to Oracle Argus Safety Application

The course provides training to the students on the features of Argus Safety, its role in fulfilling the pharmaceutical industry's toughest regulatory challenges, and how it supports drug safety business processes from an easy-to-understand user interface. Thorough case processing and discussions will allow students to gain skills regarding handling different types of cases, case processing in the software, and the highest possible quality standards to support accurate detection and analysis of drug safety signals.

Internship in Oracle Argus Safety Application

This program supplements the training provided to the students in their Oracle Argus Safety Application course. The purpose of the internship is to expose the students to an on-the-job-experience where students are given an opportunity to work with live cases. This experience is very unlike a class room setting as the students do not have access to these cases before the class and it thus enables the students to virtually experience the challenges faced by a Drug Safety Specialist in the field. Individual guidance and review of the cases processed by the faculty along with active participation and discussions will augment the hands-on learning experience of the students.

The internship program aims to develop the ability of the students to extract relevant information from varied sources to triage the assigned cases into serious or non-serious and process cases to industry standards. Additional benefits of this program for the students, as they handle the full gamut of live industry cases provided by the faculty are critical analysis and judgment skills, independent decision making and case assessment capabilities, case interpretation and data extraction abilities, data presentation and Medical writing skills along with business communication and team work skills.

Students will work on the following cases:

1. Serious cases: Any case that causes death, life threatening illness, disability, hospitalization, prolongation of hospitalization or congenital abnormality.
2. At Risk Cases: Cases where the patient had been prescribed medication for an unapproved indication, for an unapproved dosing regimen, over dose or for an unapproved age or population (male/female)
3. Lack of efficacy cases: Cases where the prescribed indication (disease for which the drug is prescribed) does not improve.
4. Study Cases: Cases involving drugs under clinical study for which a marketing authorization has not been obtained. Cases where drugs have been prescribed for compassionate use. Cases where a post marketing non-interventional study is being conducted as required by the regulatory authority for assessing the risk-benefit of the drug.
5. Spontaneous Literature cases: Published literature articles involving company products and adverse events experienced.
6. Invalid Cases: Cases that involve an unspecified patient, product, event, non-company product, unspecified number of patient, medical information queries or product complaints with no adverse events.
7. Non-serious cases: Any case that does not jeopardize the patient life and daily activities.

PART 3

Module 1: Statistics with R

This course introduces the theoretical concepts of Statistics with programming tools for Data Science. Theoretical Concepts of Data Exploration, Comparison, Theory of Probability, Data distributions, Sample size and Estimation, Univariate, Bivariate and Multivariate analysis, Tests of Hypothesis, Inferences, Contingency tables are introduced with Projects based statistical problem solving with SAS & R programming tools. There will be many case studies shown in this

class as well as a project using a data set in which the student would go through an entire Statistical experiment process and report their findings.

Module 2: Data Visualization with Tableau

This course focuses on data representation with visualizations, reporting, communication and storytelling with industry tools like Tableau, and other tools. Students work on importing data, interpreting the chart, graph and table visualizations. Then, they edit, modify and create and share reports. Finally, they prepare a project presentation of case studies with presentations.

Module 3: SQL, Spark, and Hadoop

This course starts with concepts in Structured Query Language (SQL). The course describes the specific structure of databases in their organization, and content. It then proceeds to an in-depth understanding of accessing and using data with Structured Query Language, data warehousing, and requirement gathering. Finally, the course ends with defining the architecture and design of data warehousing, and ETL (Extract, Transform, Load) strategies.

Students will practice working with and retrieving data using Structured Query Language and relational databases. Database design will be thoroughly explained in order to best understand client requirements in workplace. Hot industry topics will be discussed and how they all work with relational database management systems.

Module 4: Clinical Research and Clinical Data Management

This course introduces the concepts of Clinical research processes including good clinical practices, roles and responsibilities of a clinical research associate, understanding IRBs, informed consent process, case report forms, and regulatory compliance. Also, drug inventory management, sponsor/FDA Audit preparedness, drug returns, and site closeout responsibilities would be covered.

This course also provides practical training in the process of clinical data management. Students will develop an advanced understanding of the process, systems, techniques and documentation. Study setup to database lock concepts will be covered using sample study documentation.

Module 5: SAS Clinical and CDISC

This course will cover essential statistical and clinical research concepts, base SAS programming, and a comprehensive introduction to working with SAS Clinical data. Some of the topics

covered would be the Statistical analysis plan, and the SAS programming environment and language. SAS Clinical demonstrates how to create and manipulate data sets, import and export and manage clinical trial data as well.

The program also introduces the essentials for using SAS Clinical with industry CDISC (SDTM and ADAM) standards to register source and target tables and to create and manage jobs that transform source tables and load them into target data structures. SAS Clinical Data Integration supplies pre-defined CDISC standard definitions for SDTM and ADaM table structures and content and this program shows how to leverage those standard definitions to create jobs that transform source data from clinical studies to load those SDTM and ADaM standard structures, to validate the structure and content of those data structures based on the standards, and to generate CDISC standard define.xml files describing the SDTM domains and ADaM datasets that are part of clinical submissions.

Module 6: Projects

Clinical Trial Management

The Clinical Trial Management program prepares students for the entire spectrum of the clinical trials profession as applicable to the pharmaceutical and biotech industries and to regulatory compliance. Students are provided with additional opportunities to learn about recent advancements and specializations in e-Clinical Technology.

The program teaches students about the steps involved in a study startup, a study conduct, and a study closeout. A study startup, the first step in conducting a clinical trial, includes topics such as study feasibility and site selection, clinical trial budgets and contracts, and clinical trial protocol. The second step, study conduct, centers around topics like site monitoring visits; how and why randomization and blinding are done during clinical trials; and recruitment, retention, and compliance of patients for clinical trials.

Study closeout, the final step, covers topics such as site closeout visit, site summary analysis, the Investigational New Drug (IND) process, and the submission of the eCTD (electronic Common Technical Document) submission process required for New Drug Applications (NDA). Through case scenarios, clinical tasks, and other site management activities students will get hands on training on the Clinical Trial Management System, the Electronic Data Capture Management System, and the Electronic Trial Master File Management System.

CIP Code: 51.1005
Program Hours: 300 Clock Hours
Program Code:
Program Mode: Hybrid

Program Curriculum

Theme: Clinical Trial Management

Study Start-Up

Module 1

- Phases of the Clinical Trial
- ICH-GCP Guidelines
- Study Feasibility Site Selection

Module 2

- IRB/IEC
- Budgets
- Contracts

Module 3

- Essential Documents (Prior to Study Start)
- Financial Disclosure Form
- Clinical Trial Protocol

Module 4

- Investigator Brochure
- Informed Consent Process
- Monitoring – General introduction to all the types of visits

Study Conduct

Module 5

- Site Monitoring Visits (Include Remote/Central Risk-Based Monitoring Concept)
- Randomization/Blinding
- Recruitment/Retention/Compliance

Module 6
- Adverse Events/Serious Adverse Events
- Drug Advertisement
- HIPAA Regulations

Module 7
- Medical Devices
- Fraud/Misconduct/Potential Liability

Module 8
- FDA Inspection
- Essential Documents (During Study Conduct)

Study Close Out

Module 9
- Site Close-Out Visit (On-Site/Remote Activities)
- Statistical Analysis

Module 10
- Investigational Drug Application
- New Drug Application
- eCTD (Common Technical Document)

Module 11
- Essential Documents (After Study Close-Out)
- Risk-Based Monitoring

Module 12
- Evidence Based Medicine
- Personalized Medicine
- Big Data

20-Week Internship Program

Week 1
- Introduction to Clinical Trials
- Phases of the Clinical Trials
- ICH/GCP (E6) R2 Guidelines
- Study Feasibility Questionnaire

- Introduction to CTMS system

Week 2

- Training for CTMS system
- Setting up Sites in CTMS system
- Setting Site staff in CTMS system
- FDA Form 1572

Week 3

- Qualification Visit Confirmation Letter
- Raise Issues in CTMS system
- Generate Qualification report in CTMS system
- Generate Qualification Follow-up Letter

Week 4

- Site Initiation Visit Confirmation Letter
- Raise Issues in CTMS system
- Generate Site Initiation report in CTMS system
- Generate Site Initiation Visit Follow-Up Letter

Week 5

- IRB Approval Letter Initial and Continuing Review
- IRB approval Tracking Tool
- Budget Template
- Contract Template
- Introduction to TMF

Week 6

- Training Modules in TMF
- Upload Essential Documents
- Sample Financial Disclosure Form
- Clinical Trial Protocol Template
- Protocol Amendment Tracking Tool

Week 7

- IB Sample Template
- Training Modules in TMF
- Informed Consent Form Template
- Informed Consent Form Tracking Tool
- Introduction to Monitoring in CTMS system

Week 8

- Introduction to EDC system
- Data Entry into eCRF
- Source Data Verification
- Raise Queries
- Investigational Product Accountability using IPAL

Week 9

- Monitoring Visit Confirmation Letter
- Raise Issues in CTMS system
- Generate Monitoring Visit Report
- Generate Monitoring Visit Follow-Up Letter

Week 10

- Remote Site Management using CTMS system
- Mock Tele-Conference with Site
- Issue Resolution
- Generate Remote Site Monitoring Visit Report

Week 11

- Introduction to Global Medical Safety
- AE Data Entry in EDC system
- SAE Data Entry in EDC system
- Sample SAE Report
- SAE Reconciliation

Week 12

- Training Modules in TMF
- TMF Metrics
- TMF Placeholders
- Upload Essential Documents into TMF

Week 13

- Training Modules in CTMS system
- Update Site Staff
- Regulatory Document Tracking
- Track IRB Approvals
-

Week 14

- Introduction to FDA Inspection
- FDA.gov Resource
- Mock FDA Inspection
- Inspection Readiness Tracking using TMF

Week 15

- Introduction to HIPAA
- Sample HIPAA Compliance Form
- Sample Case Studies for Fraud, Misconduct, and Potential Liability

Week 16

- Generate Site Closeout Confirmation Letter
- IP Accountability and Reconciliation
- Sample IP Accountability Log
- Temperature Excursion Log
  Study Timelines
- Drug Destruction Form
- Generate Site Closeout report using CTMS system
- Generate Site Closeout Follow-Up Letter

Week 17

- Sample IND application
- Sample NDA application
- Upload Essential Documents using TMF
- Site Master File-TMF Reconciliation

Week 18

- Site Closeout activities in CTMS system including Site Closeout confirmation letter, Closeout Visit Report, Closeout follow-up letter
- Site Closeout activities in TMF
- Site Closeout activities in EDC system

Week 19

- Mock Site Qualification Visit in CTMS system
- Mock Site Initiation Visit in CTMS in CTMS system

Week 20

- Mock Site Monitoring Visit in CTMS system
- Mock Site Closeout Visit in CTMS system

Data Analyst

The Data Analyst program will teach students about the core functionalities, procedures, and tools necessary for data analysis. They will learn to implement algorithms for data aggregation, cleaning, and analysis; formulate appropriate analytic approaches for a problem; collect data with predictive modeling techniques; and come up with solutions for resolving data quality issues.

The role of a data analyst involves a variety of activities that include interpreting, analyzing, and visualizing data that has been acquired by an organization either by using statistical techniques or through some tool-based interface. Apart from these roles, data analysts also use established systems and methodologies for collection of data and implementation of data analysis systems.

Students will learn how to use the best tools in the industry including the Hadoop ecosystem, Spark, Python, R, SQL (Structured Query Language), and MySQL (an open source relational database management system). They will also work on real-world applications by working with business data sets, case studies, and a capstone project.

CIP Code: 11.0401
Program Hours: 75 Clock Hours
Program Code: CDA
Program Mode: Hybrid

Program Curriculum

Data Manipulation and Machine Learning with Python 15 Clock Hours

Python is an interpreted and an object-oriented programming language which is widely popular and in high demand in domains of data analysis and data science. The ease of use, scalability and dynamic binding capabilities have made it one of the most open source scripting languages for highly scalable applications in domain of data analysis and data sciences. The curriculum with introduce the functionalities of Python with a base understanding of Python constructs and working on popular libraries as may be needed for the data analysis domain.

- Data Analysis – Students will be provided hands on exposure to popular data manipulation and data analysis libraries like Pandas and Numpy. The skills that will be imparted to students will include data acquisition, data wrangling, data mining, data munging, data analysis, data modulation, feature identification, matrix operations, etc.

- Machine Learning –Students will be provided hands on exposure to popular machine learning algorithms in Python. The major library that they will work with would include SckitLearn. Machine learning is gaining popularity among employers for its predictive capability and analytical functionalities which can be helpful for businesses to have a deeper understanding and advance analytical capabilities about their data.

Data Mining/Statistical Analysis and NLP with R 15 Clock Hours

R is statistical programming language and environment which is widely used in the domain of statistical analysis, data analysis and data science. The language boasts of a wide array of libraries and functionalities in the domains of statistical computing and graphics.

- Data Mining – Students will be provided hands on exposure to overall process of data mining/statistical analysis which would include working with structured, semi-structured and unstructured data. The functionalities would include both exploratory and explanatory data mining/statistical systems.

- NLP –Students will exposed and provided knowledge of analyzing unstructured (text) data. With most new data entering the business systems in unstructured format this submodule will provide them with a hands-on experience to undertake, feature extractions, sentiment analysis, natural language processing, text analytics and similar analytical systems.

Working with SQL/MYSQL **15 Clock Hours**

Understanding and working with structured data is one of the key skills to be processed by any Data Analyst. As most transactional data is either stored or acquired in structured formats hence working with SQL/MySQL becomes an imperative prerequisite for any data analyst.

The curriculum will cover basic to moderately advance understanding and working with structured data primarily using SQL/ MySQL and moving on the advance levels of constructing stored procedures, writing triggers, query constructs and data analysis and manipulation, etc.

Working with Big Data Technology **15 Clock Hours**

Given the vast volumes of data it becomes imperative for any Data Analyst to have some base level understanding of working in Big Data environment. The curriculum will provide hands on base experience with data acquisition and analytical systems using big data technologies like Spark/Hadoop

Data Visualization Using Commercial & Open Source Tools **15 Clock Hours**

Data visualization and dashboarding are core skills for any data analyst. The module will cover the important aspects of data visualization, dashboard creation, business storytelling, visual analytics, etc. The tools that will be taught to students would include commercial tools like Tableau and/or open source tools like R environment.

An integrated capstone project will be given to the students to cover all topics covered in the module and develop a personal portfolio of work.

Data Science

The Data Science program is a highly selective program for students with a background in healthcare, mathematics, computer science, applied statistics, and science. Data scientists excel at analyzing data, particularly large amounts of data, to help businesses gain a competitive edge. The curriculum will focus on foundations of data science, statistical modeling, data mining, machine learning, and business analytics specifically in healthcare.

Students will learn how to implement algorithms for data aggregation, cleaning, and analysis. They will be able to formulate appropriate analytic approaches for a problem, collect data with predictive modeling techniques, and come up with solutions for resolving data quality issues. Students will be able to communicate data analysis findings with appropriate visualizations and presentations, and work on real-world applications through case studies, projects, and a capstone experience.

They will gain a good understanding of the programming, mathematical, statistical, and business foundations of data science. The Data Science program emphasizes the critical arc that runs from data to information, information to knowledge, and knowledge to decision making. Thus, students will learn how to work with industry tools such as R and Python. They will be able to select and apply appropriate data analysis techniques to a variety of tasks, including big datasets. Students will be prepared for the demands of the highly specialized skill sets they will acquire that are necessary for making intelligent decisions in data science.

CIP Code: 11.0401
Program Hours: 300 Clock Hours
Program Code: CDS
Program Mode: Hybrid

Program Curriculum

CORE

Module 1: Statistics with R

1. Descriptive statistics
2. Data Types
3. Discrete and Random Variables
4. Probability, Distributions, Density Functions and their applications inhealthcare

5. Outliers
6. Data Display (Histograms, Boxplots, Multivariate chart, run chart, Scatter plot, etc.)
7. Linear Association, Correlation, Multicollinearity, Coefficient of Determination
8. Outliers and Influential Points
9. Hypothesis testing
10. Model Fit & Model Assumptions
11. Data Transformation
12. Simple Linear Regression
13. Categorical Analysis & Multiple Linear Regression
14. Logistic Regression (logit model)

Module 2: Data Visualization with Tableau

1. Basic Charts for Visualization
2. Visualizing Relationships with Advanced Graphs
3. Creating Dashboards
4. Storytelling & Reports
5. Data Visualization using Tableau
6. Combination of tools R and Tableau

Module 3: SQL, Spark and Hadoop

1. Structured Query Language (SQL)
2. MySQL and SQL Server
3. Hadoop Fundamentals
    - Introduction to Hadoop
    - MapReduce
    - The Hadoop Distributed Filesystem
    - YARN
    - Hadoop, I/O
    - MapReduce
    - Developing a MapReduce Application.
    - Setting Up the Development Environment
    - How MapReduce Works
    - MapReduce Types and Formats
    - MapReduce Features
    - Hadoop Operations
    - Setting Up a Hadoop Cluster
    - Administering Hadoop
    - Related Projects

- Sqoop
- Pig
- Hive
- Crunch
- Spark
- HBase
- ZooKeeper

Module 4: Time Series Analysis, Forecasting and Variability reduction with Python

1. Stochastic Stationary & Non-Stationary Models
2. Auto Regressive Models
3. Moving Average Models
4. ARIMA and Seasonal Models
5. Forecasting seasonal/non-seasonal discrete time series fitting models to time series data
6. Design of Experiments - One way ANOVA, Two Way ANOVA, interaction between factors, Randomization, Orthogonality, Factorial Design
7. Sampling Techniques - Simple Random, Stratified, Cluster sampling, preparing surveys and data analysis
8. Statistical Process Control - Understanding the process and customer specification limits, seven basic tools of quality control, variation, ANOVA, process capability.

Module 5: Machine Learning with Python

1. Data Basics - data structure, CART, PERT, data collection & preparation
2. Bayesian Learning
3. Linear Classification
4. Decision Trees & Random Forests
5. Regression
6. Non-linear classification with Neural Networks and Kernels
7. Model Validation
8. Feature Selection
9. Cluster Analysis
10. Text Mining
11. Case Studies in Healthcare
12. Concepts in Relational Databases (RDBMS)
13. CAP Theorem
14. Manipulating Data, Joins, Functions

Module 6: Capstone Project

The project will be on one of the topics from above as per Faculty requirements.

Drug Safety and Pharmacovigilance

The Drug Safety and Pharmacovigilance program is a very unique job-oriented training program that provides a thorough understanding of the basic concepts of drug safety and risk management throughout the process of drug development and its life cycle in the open market either as a patent or generic drug. This exposure prepares students to understand and appreciate the various types and grades of Adverse Events.

Students are trained to correlate the Adverse Event with any vital and systemic abnormality resulting from the Adverse Event and understand the causal relation of the drug known as Adverse Drug Reaction (ADR). Students will also be trained in the analytical skills needed to differentiate between the progress of the disease and ADR as a signal.

This program will focus on the regulatory issues across global governmental agencies like the FDA, ICH, and others that improve safety. Practical training will also be provided on industry-based tools on topics such as data entry, case processing, MedDRA, and WHO-DD coding, and SAE narrative writing.

CIP Code: 51.9999
Program Hours: 150 Clock Hours
Program Code: ?
Program Mode: Hybrid

Program Curriculum

Module 1: Introduction to Drugs, Safety and its Regulations

Topics covered in this session include the following:

1. Drug Development Process
2. Ethics of Human Subjects Protection
3. Good Clinical Practice in Clinical Trials

Drug development is the process of bringing a new pharmaceutical drug to the market once a lead compound has been identified through the process of drug discovery. It includes preclinical research on animals, clinical trials on humans, and the step of obtaining regulatory approval to market the drug. This module will educate students about the basic process of drug development and the regulatory and compliance processes that ensure consumer safety.

Module 2: Adverse Events Reporting and Post-marketing Activities

Topics covered in this session include the following:

1. Adverse Events-1 In Detail
2. Adverse Events-2 MedWatch, Voluntary Reports
3. Adverse Events-3 Triage and ICSR Generation

Module 3: Introduction to Oracle Argus Safety Application I

Topics covered in this session include the following:

1. Pharmacovigilance Overview
2. Regulatory Guidelines
3. Argus Safety Overview
4. Argus Safety Database
5. Case Processing in Argus Safety
6. MedDRA and WHO-DD Overview

The course provides training to the students on the features of Argus Safety, its role in fulfilling the pharmaceutical industry's toughest regulatory challenges, and how it supports drug safety business processes from an easy-to-understand user interface. Thorough case processing and discussions will allow students to gain skills regarding handling different types of cases, case processing in the software, and the highest possible quality standards to support accurate detection and analysis of drug safety signals.

Identity and Access Management

The Identity and Access Management (IAM) program will introduce students to the framework of policies and technologies for ensuring that the proper people in an enterprise have the appropriate access to technology resources. Students will learn about the basics of IAM on the Windows environment and on Azure, a cloud computing service. They will cover topics such as the Active Directory (AD) for the Windows Server and Azure, learn how to integrate Software as a Service (SaaS) apps, master Windows 10, and review the Active Directory Federation Services

(ADFS) - a software component that provides users with single sign-on access to systems and applications located across organizational boundaries.

Students will gain a thorough understanding of a myriad of concepts including the implementation of domain controllers, certificate-based authentication using ADFS, managing Azure AD with Furthermore, students will be able to explore single sign-on (SSO) options in applications, integrate AD with Azure AD via Pass Through Authentication (PTA), troubleshoot user string checking, compare Windows Image Acquisition (WIA) with Fulfillment by Amazon (FBA), among many other tasks. debugging tool that logs all HTTP(S) traffic between a user's computer and the Internet). They will be able to configure password and account policies, install and configure Wireless Application Protocol (WAP) and build trust with ADFS, demonstrate self-service password reset, and implement Mobile app for Azure multifactor authentication.

Furthermore, students will be able to explore single sign-on (SSO) options in applications, integrate AD with Azure AD via Pass Through Authentication (PTA), troubleshoot user string checking, compare Windows Image Acquisition (WIA) with Fulfillment by Amazon (FBA), among many other tasks.

CIP Code: 11.0103
Program Hours: 4 to 6 weeks
Program Code:
Program Mode: Hybrid

Program Curriculum

Module 1: Windows Server Active Directory Fundamentals

- Introduction to Active Directory
- Implementation of Domain Controllers
- Sites & Subnets
- Multi Domain Forest
- GPO / FSMO Roles
- Practicals - DEMO
- Student Mandatory Labs
- Installation of Domain Controllers ,DNS ,Certificate Server
- Installation of Additional Domain Controllers
- Configure Member Server to Domain
- Creation of Group Policy
- Configure Password /Account Policy
- Creation of Users/Groups and OU

- Creation of Site and install DC in remote Site

Module 2: Introduction to Azure Active Directory

- What is Azure Active Directory
- Active Directory Overview
- Azure Active Directory Subscription Levels

- Azure Active Directory Editions
- Managing Azure Active Directory With PowerShell
- Practical - DEMO
- Student Mandatory Labs
- Walk-through of the Azure AD Console
- Custom Domain registration
- Guest account creation and invite

Module 3: Managing Active Directory

- Guest account creation and invite
- Role-Based Access Control
- Managing Domain in Active Directory Domains
- Managing Users And Groups
- Student Mandatory Labs
- Walk-through of the Azure AD Console
- Create users and Group (Dynamic and Assigned)
- Demonstrate Self-Service Password Reset (SSPR)
- RBAC Creation , Security groups creation Demonstrate Self-service Group Membership

Module 4: ADFS (Windows Server 2016/2012)

- Overview of ADFS
- ADFS Deployment (WAP/ADFS Server)
- Knowledge on SAML ,WS-FED and openID Connect authentication protocols
- Manage SSL Protocols in ADFS
- Configuring inhouse SSO in ADFS
- ADFS FARM Concepts
- Certificate-Based authentication using ADFS
- Azure MFA using ADFS
- Practicals -DEMO
- Student Mandatory Labs
- Install ADFS Server,Certificate Templates
- Configure the Relaying Trust ,Build a Claims Aware Application

- Install of WAP Server
- Installed and Configure WAP and Build trust with ADFS
- X-ray claim with ADFS

Module 5: Azure Active Directory in a Hybrid Solution

- Planning for a Hybrid Solution

- Determine identity requirements for your hybrid identity Solutions
- Determine Directory synchronization requirements
- Integrate Office 365 With Azure AD
- Passthrough Authentication
- Student Mandatory Labs
- Install and configure AAD Connect
- Integrate AD with Azure AD via Password Hash Synchronization (PHS)
- Integrate AD with Azure AD via Pass Through Authentication (PTA)

Module 6: AD Privilege Access

- Azure Active Directory Services
- Privileged Identity Management
- Self-Service Password Reset
- Azure Conditional Access
- Azure Identity Protection
- Self-Service Group Management
- Multi-Factor Authentication
- Implement Mobile app for Azure Multi-Factor Authentication
- Student Mandatory Labs
- Access to on-premises applications through AAD Application Proxy
- Demonstrate Cloud MFA
- Configure of Azure Domain Services
- Azure Conditional Access

Module 7: Integrate SaaS Apps

- Integrating SaaS Applications in Azure AD
- SaaS Application Integration Overview
- Installing SaaS Overview
- Application Proxy Connector
- Managing Access
- Student Mandatory Labs
- Publish Saas Applications

- X-ray claim with AAD
- WSFed app with AAD
- Openid Connect – AAD
- Configure Application Connector
- Explore Various SSO Options in Applications

Module 8: Windows 10

- Windows 10 Hello Business
- Active Device Registration
- Student Mandatory Labs
- Demonstration of Hybrid AD Join
- Demonstration of Azure Active Directory Domain Join (AADJ)
- Demonstration of Device Registration.

Module 9: Troubleshooting Topics

- Analyzing Fiddler traces
- Student Mandatory Labs
- capture the AAD managed account scenario
- SP initiated scenario From Internet
- Compare WS-Fed with SAML
- Compare WIA with FBA
- User String Checking
- Azure MFA lab with Fiddler
- HTTP Cookie behavior

Java Full Stack

Java, the most popular programming language in use, is a general-purpose programming language that is class-based, object-oriented, and specifically designed to have as few implementation dependencies as possible. It is intended to let application developers “write once, run anywhere” (WORA), meaning that compiled Java code can run on all platforms that support Java without the need for recompilation. Java applications are typically compiled to “bytecode” that can run on any Java virtual machine regardless of the underlying computer architecture.

Students will be trained on the fundamentals, web application, and database application of Java. They will cover topics such as introduction to Java programming, multithreading, generating content with Servlets, maintaining State in Java web applications, handling complex object relationships, web services overview, and securing web services. They will also learn about Jnuit, Jenkins, Angular and Typescript, controllers, modules and directives.

CIP Code: 11.0103
Program Hours: 250 Clock Hours
Program Code:
Program Mode: Hybrid

Program Curriculum

Module 1: Core Java

- Introduction to Java Programming
- Getting Started with Java and Eclipse
- Language Fundamentals
- Objects and Classes
- Using Java Objects
- Inheritance in Java
- Data Structures
- Advanced Inheritance and Generics
- Packages
- Exception Handling
- Core Collection Classes
- Multithreading
- I/O File, Buffer
- Object Lifetime & Garbage Collection

Module 2: Web Development Concepts

- Introduction and Overview
- Generating Content with Servlets
- Accessing Databases with Servlets
- Maintaining State in Java Web Applications
- Creating Java Server Pages (JSP)
- JSP and Servlet Architectures

Module 3: Development Using Spring and Hibernate

- Introducing the Spring Framework
- Constructing an Effective Data Access Tier with Spring
- Building a Web Tier with Spring MVC
- Persisting Objects with Hibernate

- Handling Complex Object Relationships
- Optimizing Data Access

Module 4: REST and SOAP Web Services

- Web Services Overview
- Defining SOAP Messages with WSDL
- Implementing Code – First Web Services
- Generating Contract – First Web Services
- Building RESTful Web Services
- Securing Web Services

Module 5: Testing

- Unit Testing Framework – Jnuit

Module 6: DevOps

- CI/CD Concepts
- Jenkins

Module 7: Angular

- Introduction to Angular and Typescript
- Modules and Directives
- Models and Data Binding
- Controllers
- Events and Forms

Java Web Development

The Java Web Development program will teach students about the basic concepts of Java as well as the advanced programming techniques required by the industry. Java web developers use Java to create applications found across the Internet through multiple platforms such as desktop computers and mobile phones. They design and create websites, maintain client websites, troubleshoot problems, and write code for Java-enabled websites.

This program will cover topics such as NodeJS Platform, REST Services, CLI, App Modules, Event Binding, Understanding Error Messages, Observables with RxJS, Form Handling, Pipes, Optimization Techniques and Performance Improvements. Students will also learn about Karma, CondeceptJS for ATDD, Git Concepts and Day-to-Day Operations, NgRx Store Concepts, AOT, Web

Pack, and Memory Leaks.

CIP Code: 11.0103
Program Hours: 250 Clock Hours
Program Code:
Program Mode: Hybrid

Program Curriculum

Module 1: Core Java

- Introduction to Java Programming
- Getting Started with Java
- Eclipse
- Language Fundamentals
- Objects and Classes
- Using Java Objects
- Inheritance in Java
- Advanced Inheritance and Generics
- Packages
- Exception Handling
- Input/Output Streams
- Core Collection Classes

Module 2: Web Development

- Introduction and Overview
- Generating Content with Servlets
- Accessing Databases with Servlets
- Maintaining State in Java Web Applications
- Creating Java Server Pages (JSP)
- JSP and Servlet Architectures

Module 3: Spring and Hibernate

- Introducing the Spring Framework
- Constructing an Effective Data Access Tier with Spring
- Building a Web Tier with Spring MVC
- Persisting Objects with Hibernate
- Handling Complex Object Relationships

- Optimizing Data Access

Module 4: REST and SOAP Web Services

- Web Services Overview
- Defining SOAP Messages with WSDL
- Implementing Code – First Web Services
- Generating Contract – First Web Services
- Building RESTful Web Services
- Securing Web Services

Module 5: Getting Started

- ES Script (ES6/7/8) & Type Script
- Transpile
- NodeJS Platform
- NPM
- RWD
- PWA – Service Workers, Offline Capabilities, etc.
- REST Services
- OAUTH2/JWT Concepts

Module 6: Angular

- CLI
- Versions & Comparisons
- Components (Nesting, Templates, Styles, etc.)
- Custom Components
- App Modules
- Data Binding
- Property Binding
- Event Binding
- Two-way Binding
- Directives (ngFor, nglf, ngClass, ngStyle, ngSwitch, etc.)

Module 7: Debugging

- Understanding Error Messages
- Debugging in the Browser
- Using Augury Plugin

- Services & Dependency Injection
- Routing (Router, Routes, Links, Paths, Programmatic Routing, Route Parameters, Nested Routes)
- Observables with RxJS
- Form Handling
- Pipes
- Http Requests from Angular (Synchronous/Asynchronous)
- Authentication and Integration with Auth Provider (Auth0 or Okta or Google)
- Optimization Techniques/Performance Improvements

Module 8: Testing

- Karma
- Jasmine/Mocha
- CodeceptJS for ATDD
- Cucumber-JS for BDD

Module 9: DevOps

- Types of Version Control Systems (Centralized vs. Distributed)
- Git Concepts and Day to Day Operations
- Build and Deploy using Webpack
- Localization and Internationalization
- Security Aspects like CSRF, CORS; Impact of Using Local Storage/Session Storage, etc.; Touch Upon OWASP
- NgRx Store Concepts

Module 10: Key Performance Parts

- AOT
- Tree Shaking
- Lazy Loading
- Web Pack
- Memory Leaks

Medical Science Liaison

The Medical Science Liaison program is tailor-made for pharmacists and physicians who are interested in developing new careers in pharmaceutical and biotechnology companies. A medical

science liaison (MSL) is a healthcare consulting professional who is employed by pharmaceutical, biotechnology, medical device, and managed care companies to establish and maintain peer-to-peer relationships with Key Opinion Leaders (KOLs) at major academic and health institutions.

Students will cover topics such as an overview of the pharmaceutical industry, an introduction to Health Economics Outcome Research (HEOR), abstract and medical writing, an introduction to field-based medical teams and the role of the MSL, the value of Advisory Boards in changing the landscape of medical affairs, an introduction to regulatory affairs, the tiers of compliance regulations, and presentation and communication skills.

They will also learn about the medical device and diagnostics industries, evidence-based medicine, the drug development process and clinical trial designs, the purpose of post-marketing research, risk evaluation and mitigation strategies (REMS), medication safety and pharmacovigilance, publication practices, grant and investigator-initiated study funding and process, emotional intelligence, and how to build long-term relationships. The program will equip students with the project management, research, and counseling skills necessary to be effective medical science liaisons in any organization.

CIP Code: 51.2799
Program Hours: 300 Clock Hours
Program Code:
Program Mode: Hybrid

Program Curriculum

Module 1

The Pharmaceutical Industry

1. Introduction to the Pharmaceutical Industry
2. History and Development
3. Publicly Traded vs. Private Companies
4. Global Needs Driving the Growth of the Pharma Industry
5. The Different Functions Within the Pharmaceutical Industry (Drug Manufacturing, Supply Chain, Regulatory Agencies, International Regulatory Bodies)
6. Pharmaceutical Industry Organizational Structure and Organization Function
7. Drug Discovery: Research and Development (R&D)
8. The Drug Development Process – Path to Drug Approval
9. Drug Advertising
10. Generic Drugs

11. Problem Reporting
12. Active Surveillance
13. Staying Competitive

Medical Device Industry

1. Introduction to the Medical Device Industry
2. Market Segmentation Categories
3. The Device Business Market
4. Exportation of Medical Devices
5. Global Market Growth Drivers
6. US Medical Device Industry Constraints
7. Medical Device Regulatory High Points
8. Medical Device Pathway

Diagnostics Industry

1. The Diagnostics Industry
2. Segments of In Vitro Diagnostics (IVDs
3. Molecular Diagnostics
4. Point-of-Care (POC) Diagnostics
5. Regulation of IVDs
6. Classification of IVDs

Module 2

Health Economics Outcome Research

1. Introduction to Health Economics Outcome Research (HEOR)
2. Models of Pharmacoeconomics
3. Assessment of Costs and Outcomes
4. Conducting a Pharmacoeconomic Analysis
5. Health Outcome Research
6. Quality of Life Measures

Evidence-Based Medicine

1. What is Evidence-Based Medicine (EBM)
2. Five Steps to Practice EBM
3. Study Designs
4. Evidence Hierarchy

5. Classification of Literature Resources

Drug Development Process and Clinical Trial Designs

1. Introduction to Clinical Trials
2. Importance of Clinical Trials
3. Clinical Trial Structural Designs
4. Clinical Trial Hypothetical Designs
5. Clinical Trial Parameters
6. Statistical Analysis
7. Diagnostics Tests
8. Bias and Confounding in Research

Module 3

Phase IV/Post-Marketing Studies

1. Purpose of Post-Marketing Research
2. Advantages and Disadvantages of Post-Market Research
3. Types of Post-Marketing Studies
4. FDA-Mandated vs. Non-FDA-Mandated
5. Roles of Medical Affairs in Post-Marketing Activities of Drugs

Risk Evaluation and Mitigation Strategies (REMS)

1. Introduction to REMS
2. Examples of the Types of Risk REMS Requirements Aim to Mitigate
3. Determining When a REMS is Needed
4. What the FDA Takes into Consideration When Identifying the Need for REMS
5. REMS Elements
6. Elements to Assure Safe Use (ETASU)

Medication Safety and Pharmacovigilance

1. Safety Signals
2. Adverse Events
3. Adverse Drug Reactions
4. FDA Premarket and Postmarket Safety

Module 4

Abstract and Medical Writing

1. Introduction to Abstracts
2. Purpose of Writing an Abstract
3. Types of Abstracts
4. Effective Abstract Writing for Scientific/Research Papers
5. Components of the Abstract
6. Medical Writing in the Health Care Industry
7. Types of Medical Writing
8. General Steps in Writing Scientific Documents

Publication Practices

1. Introduction to Publications in Medical Affairs
2. Landmarks in Publications
3. Publications Workflow
4. The Scientific Platform
5. Working with Authors

Medical Information

1. Medical Information: Structure
2. Roles Within Medical Information
3. Medical Information Stakeholders
4. Medical Information Core Responsibilities
5. Scientific Review Committee
6. MI Key Challenges and Opportunities

Medical Science Liaisons and Field Based Medical Teams

1. Medical Science Liaisons: Here and Now
2. Introduction to Field Based Medical Teams and the Role of the MSL
3. Key Opinion Leaders
4. Geographic Coverage by MSL Teams
5. Roles Within an MSL Organization
6. Communication and Meeting Preparation
7. Networking and KOL Identification
8. Clinical Research Support

9. Maintaining Scientific Accuracy and Product Initiative Support
10. MSL Key Challenges and Opportunities

Grant and Investigator-Initiated Study Funding and Process

1. Grants Process
2. Investigator Initiated Studies (IIS)
3. Funding Opportunities and Sources

Advisory Boards

1. Role of Advisory Boards
2. Challenges and Key Elements to the Success of Advisory Boards
3. Members of Advisory Boards

4. Value of Advisory Boards in Changing the Landscape of Medical Affairs

Module 5

Regulatory Affairs

1. Introduction to Regulatory Affairs
2. Regulatory Affairs in the Medical Device Industry
3. Medical Device Classification
4. Performance Standards
5. Medical Device Filing Types
6. Regulatory Affairs in the EU and Canadian Pharmaceutical Industries

Compliance

1. First Tier

    - Regulations and Subparts (FDA 21 CFR)
    - Current Good Manufacturing Practices for Manufacturing
    - FDA 21 CFR Parts 211 Current Good Manufacturing Practices for Finished Products
    - FDA 21 Parts 280 Quality System Regulation for Good Manufacturing Practices

2. Second Tier

    - Compliance Regulations and Subparts (FDA 21 CFR Part 50 Protection of Human Subjects

- FDA 21 CFR Part 56 Institutional Review Board
- FDA 21 CFR Part 58 Good Laboratory Practice for Non-Clinical Laboratory Studies (GLPs)

3. Third Tier

- Compliance Regulations and Subparts (FDA 21 CFR Part 7 Enforcement Policy)

Module 6

The MSL Presentation & Communications Skills

a. Effective MSL Presentation Skills
b. Effective KOL Interactions
c. Emotional Intelligence

d. Communication Skills
e. Insight Gathering Skills
f. Making Complex Slides Simpler to Understand
g. Dealing with Difficult Stakeholders More Confidently
h. Objection Handling Skills
i. Building Long-Term Relationships

Regulatory Affairs

The Regulatory Affairs program trains students on how to deal with regulatory compliance in the pharmaceutical industry. The profession is a specialized pursuit within the pharmaceutical and biotechnology sectors that interacts with global, federal, state, and local regulatory agencies to ensure that the licensing, registration, development, manufacturing, marketing, and labeling of pharmaceutical products are conducted in compliance with all applicable rules.

Students will learn about global regulatory affairs and ethics, global regulatory strategy in the development of drugs and biologics, global regulatory strategy in the development of devices and diagnostics, clinical research for regulatory affairs, the definition and life cycle of pharmaceuticals and medical devices, regulatory medical writing, regulatory compliance, and the role of the regulatory professional.

They will cover, in depth, topics such as fundamental ethical principles, the ethics of human clinical research, elements of regulatory strategy, medical device rules in different regions, protocol development, study design, the healthcare product life cycle, advertising, labeling, pre-

and post-marketing compliance, the investigational new drug application (IND), the 510(k) premarket notification to the U.S. Food and Drug Administration (FDA), and the Common Technical Document (CTD).

Regulatory professionals play critical roles in the health product life cycle from development through post-approval. They track regulations, advise on the legal and scientific restraints and requirements; and collect, collate, and evaluate scientific data. They give strategic and technical advice at the highest levels in their companies, making important contributions both commercially and scientifically to the success of a development program and the company overall.

CIP Code: 51.2002
Program Hours: 300 Clock Hours
Program Code:

Program Mode: Hybrid

Program Curriculum

Introduction to Global Regulatory Affairs and Ethics

This course will serve as a foundation for the entire program and is designed to provide students with a framework necessary to develop an integrated understanding of regulatory affairs. covering U.S. and international legislation and regulatory processes guidelines, as well as the pivotal role that regulatory affairs leaders play in developing products, navigating the regulatory review and approval process, and contributing to keeping products on the market. Consumers today expect and demand integrity, honesty and transparency.

The course identifies and analyzes ethical issues regulatory professionals may encounter and provides a general introduction to complex concepts, principles and theories, including bioethics and legal principles. It highlights ethical issues in areas of product development, compliance and clinical testing.

- Lesson 1: The Development of Fundamental Ethical Principles
- Lesson 2: Fundamental Ethical Principles
- Lesson 3: Ethics—Human Clinical Research
- Lesson 4: Industry Compliance—Focus on Product Types
- Lesson 5: Educational Activities

Global Regulatory Strategy in the Development of Drugs and Biologics

Focuses on the development and evaluation of global regulatory strategies that support drug and biologic product development. In this course we analyze the critical elements of the product life cycle in the determination of a regulatory strategy, asses the roles of non-clinical and clinical data in determining regulatory strategy, appraise approaches for integrating strategic business needs into regulatory planning and evaluate the role of post-marketing efforts in shaping regulatory strategy.

This course provides a basic understanding of the challenges and goals confronting a regulatory professional when defining a global regulatory strategy. It provides an examination of the regulatory considerations in the major regions of the world where marketing applications are pursued and compares the application requirements in these regions. It describes regulatory tools, discusses reimbursement considerations and how they may affect strategy development, from both a global and regulatory perspective. Finally, the course provides insight into the role of the regulatory professional in global, cross-functional strategy teams and guidance for

effective interfacing with team members.

- Lesson 1: Overview of Drug Development During the Past Decade
- Lesson 2: Elements of Regulatory Strategy
- Lesson 3: Understanding the Requirements of a Global Strategy team

Global Regulatory Strategy in the Development of Devices and Diagnostics

This course provides a framework for the development and evaluation of the regulatory affairs strategies that support device and diagnostics development. Objectives for this course are to analyze and evaluate the principle components of global regulatory strategy for devices and diagnostics, examine the regulation of medical devices through an epidemiological lens and analyze essential considerations associated with specific classifications or specialty areas of medical devices.

This course provides a basic description of global regulatory strategy for medical devices and explains the relationships between regulatory strategy and product development. It offers guidelines for developing successful global strategies for medical devices, including definitions and classifications worldwide, elements of regulatory strategy, sources of competitive and regulatory intelligence, selection of development and product approval pathways and suggestions for professional development.

- Lesson 1: Medical Device Rules in Different Regions
- Lesson 2: Regulatory Strategy Elements
- Lesson 3: Regulatory Documentation
- Lesson 4: General Regulatory Strategy

Clinical Research for Regulatory Affairs

The course introduces students to the planning and conduct of clinical trials. It provides an overview of clinical trials terminology and discusses issues related to clinical trial design. It discusses the components of a clinical trial including considerations regarding planning and carrying out a study. In the course we evaluate alternative clinical trial design options as conduits for achieving regulatory approval.

- Lesson 1: Protocol Development
- Lesson 2: Study design
- Lesson 3: Post Marketing Surveillance and Evaluation
- Lesson 4: Assessment of Regulatory submissions

Pharmaceuticals: Definition and Lifecycle

Drugs and biologics go through a long and complex process of development before being made available for the treatment or prevention of diseases. This process involves a wide range of experts, including chemists, pharmacists, medical doctors and clinicians as well as professionals in areas such as regulatory affairs, legal and marketing. Whether you are considering a career in one of the many functional areas involved in pharmaceutical development, or simply seeking a better understanding of the pharmaceutical business, this course will provide an introduction to the pharmaceutical industry, the drug development process, and regulatory requirements governing the pharmaceutical industry.

This course also provides an introduction to the lifecycle of drug products, from discovery to on-market support. You will learn the basic terminology used in the pharmaceutical industry as well as key regulatory principles and processes governing the stages in the development of a pharmaceutical product. Stages covered will include discovery of a new molecule, nonclinical and clinical trials, manufacturing and formulation development, regulatory approval and on- market support.

- Lesson 1: Definition and History
- Lesson 2: Product Lifecycle
- Lesson 3: Regulatory Requirements

Medical Devices: Definition and Lifecycle

Medical devices go through a long and complex process of development before being made available for therapeutic or diagnostic use. This process involves professionals from varied backgrounds such as scientists, clinicians, regulatory specialists, legal experts and business specialists.

This course gives a basic introduction to medical devices and general aspects of product and regulatory lifecycles. It also provides a brief history of medical device regulation and information on basic regulatory principles and concepts as they apply to medical devices. This course lays the foundation for a more in-depth study of medical devices and how they are regulated.

- Lesson 1: Medical Device Definition and History
- Lesson 2: Product Lifecycle
- Lesson 3: Regulatory Requirements

Regulatory Medical Writing: Pharmaceuticals, Biologics, Medical Devices and Investigational Applications

Regulatory writing is an integral part of the product development and approval process and plays a crucial role in speeding product submission and supporting compliance. This course will provide an overview of some of the more complex documents prepared by regulatory and medical writers, with a focus on the Common Technical Document (CTD). Key considerations associated with writing submissions in CTD format, including region-specific considerations for clinical sections in US New Drug Applications (NDA), US Biologics License Applications (BLA) ,EU Marketing Authorization Applications (MAA), Investigational New Drug Application (IND), Canadian Clinical Trial Application (CTA) and Investigational Medicinal Product Dossier (IMPD), as well as those required for investigational devices such as the Investigational Device Exemption (IDE), European CTA and Investigational Testing Authorization (ITA).will be discussed. You will be introduced to the components of each of these application types and learn techniques for improving document quality in order to advance your career as a medical writer.

- Lesson 1: Common Technical Document (CTD)
- Lesson 2: New Drugs Application (NDA)
- Lesson 3: Biological License Application (BLA)
- Lesson 4: Marketing Authorization Application (MAA)
- Lesson 5: Premarket Approval (PMA)
- Lesson 6: 510(k) Premarket Notification
- Lesson 7: Investigational New Drug Application (IND)
- Lesson 8: Investigational Device Exemptions (IDE)
- Lesson 10: Investigational Testing Authorization (ITA)

- Lesson 11: Investigational Medicinal Product Dossier (IMPD)

Regulatory Compliance

This course focuses on the analysis and evaluation of regulatory affairs compliance strategies and guidelines. Topics include pre- and post-marketing compliance, labeling, advertising, and required reporting. In this course, we identify and assess regulatory requirements, policies and guidelines associated with GXP regulatory compliance issues. Students are required to critically analyze regulatory compliance issues and to integrate and develop implementation strategies for ensuring regulatory affairs compliance in medical product manufacturing, development, labeling, and marketing. Students will need to demonstrate their ability to craft written regulatory communications including root cause analysis and corrective and preventive actions (CAPAs).

- Lesson 1: Pre and post marketing compliance
- Lesson 2: Labeling
- Lesson 3: Advertising
- Lesson 4: Required reporting

Role of the Regulatory Professional

Regulatory professionals play critical roles in the health product lifecycle, from development through post-approval. The regulatory professional's job is to keep track of the ever-changing regulations in all of the regions or countries in which the company wishes to distribute its products. Regulatory professionals are responsible for presenting registration documents to regulatory agencies and carrying out all subsequent negotiations necessary to obtain and maintain marketing authorization for the products concerned.

Regulatory professionals also advise on legal and scientific constraints and requirements, and collect, collate and evaluate the scientific data generated by research and development colleagues. They give strategic and technical advice at the highest levels in their companies, making important contributions both commercially and scientifically to the success of a development program and the company overall. Regulatory is a dynamic discipline that brings the individual into contact with almost all of a company's various departments and disciplines.

This course discusses the evolution of the regulatory profession and the professional's roles and responsibilities. It also briefly outlines the critical events and their impact for each product lifecycle stage for drugs, biologics and medical devices.

- Lesson 1: The Regulatory Professional
- Lesson 2: The Regulatory Profession

- Lesson 3: The Healthcare Product Lifecycle

SAS Clinical

Clinical SAS programming is used for clinical data integration, organizing, standardizing, and managing clinical research data and metadata. This program provides the foundation needed to ensure standard, trusted clinical data to support strategic analyses such as cross-study and advanced safety analysis. With SAS clinical knowledge, students can gain both speed and efficiency by automating repeatable clinical data integration and significantly influence their competitive standing in the marketplace.

This program will cover essential statistical and clinical research concepts, base SAS programming, and a comprehensive introduction to the SAS Clinical Data Integration solution. SAS Clinical Data Integration relies on SAS Data Integration Studio to provide centralized metadata management using the SAS Metadata Server and the tools that it provides to visually transform data. Students will also be introduced to the clinical standards and principles of the Clinical Data Interchange Standards Consortium (CDISC, a nonprofit standards developing organization), including the SDTM and ADaM data models.

Students will also learn about the concepts of clinical research processes including good clinical practices, roles and responsibilities of a clinical research associate, regulatory compliance, drug inventory management, and site closeout responsibilities. In-depth analyses of Institutional Review Boards (IRBs), the informed consent process, case report forms, and drug returns will also be covered. Finally, students will be given practical training in the process of Clinical Data Management so that they develop an advanced understanding of the process, systems, techniques, and documentation.

CIP Code: 51.1005
Program Hours: 130 Clock Hours
Program Code:
Program Mode: Hybrid

Program Curriculum

Module 1: Clinical Research and Clinical Data Management

This module covers clinical research and clinical data management processes in-depth so that students will be able to accomplish the following objectives:

- Understand in-depth the need for clinical trials and good practice trials.

- Master the roles and responsibilities of sponsors, principal investigators (PI), regulators, clinical research coordinators.
- Grasp the principles of The Health Insurance Portability and Accountability Act (HIPAA), Institutional Review Boards (IRBs), and the informed consent process, and prepare trial sites and personnel for protocol.
- Follow the process for subject recruitment, screening, correct reporting, and compliance.
- Comprehend the drug development and clinical research processes.
- Know how to use the minimum standards, best practices, and standard operating procedures for a Data Management Plan.
- Recognize the various standards used in clinical data management including forms management data privacy and HIPAA.
- Make sense of data entry, validation, and Data Clarification Forms (DCF) management.

Module 2: SAS Clinical and CDISC

This module will cover the essential statistical and clinical research concepts, base SAS programming, and a comprehensive introduction to the SAS Clinical Data Integration solution. Students will be able to accomplish the following objectives after completing this module:

- Import and export raw data files.
- Manipulate and transform data, and combine SAS data sets.
- Create basic details and summary reports using SAS procedures.
- Identify and correct data, syntax, and programming logic errors.
- Use Output Delivery System.
- Deduce how to work with the clinical standards and principles of CDISC including the SDTM and ADaM data models.
- Make sense of advanced techniques in transforming and converting clinical data and reporting clinical trial results.
- Fathom how to validate clinical trial data reporting before submitting to federal organizations such as the Food and Drug Administration (FDA).

UI/UX Angular

User Interface (UI) is the series of screens, pages, and visual elements – like buttons and icons – that enable a person to interact with a product or service. User Experience (UX) is the internal experience that a person has as they interact with every aspect of a company's products and services. Angular is an application framework, which means a method for structuring code that makes it easier to build applications using web technologies. It is a "superheroic" JavaScript framework for building single-page web applications. Angular empowers developers to build applications that live on the web, mobile, or the desktop.

This program will cover, among other topics, core JavaScript syntax, how to add interactivity with HTML, an architectural overview of Angular, components of UI, asynchronous behavior, and additional capabilities including directives.

CIP Code: 11.0103
Program Hours: 250 Clock Hours
Program Code:
Program Mode: Hybrid

Program Curriculum

Module 1: Core JavaScript Syntax

- Architecture & Implementation
- Functions & Objects

Module 2: Adding Interactivity with HTML

- DOM Manipulation and Asynchronous Processing

Module 3: Angular Introduction

- Architectural Overview
- Typescript

Module 4: UI Components

- Define and Control Component
- Interaction and Events
- Dependency Injection
- Modularity and Data Manipulation
- Building Interactivity

Module 5: Asynchronous Behavior

- Responsiveness in App
- Rest Service Interaction

Module 6: Additional Capabilities

- Directives

SCHOOL CONTACT INFORMATION

Department	Email Address
Accounting	Accounting@sollers.edu
Admissions	Admissions@sollers.edu
Compliance	Compliance@sollers.edu
General Questions	Info@sollers.edu
Human Resources	HR@sollers.edu
Program Management	Program@sollers.edu
Student Services	Studentservices@sollers.edu
Student Services (Life Sciences)	Clinicalresearchta@sollers.edu
Student Services (IT)	SS.ds@sollers.edu

PROGRAM TUITION

Associate to Bachelor's Programs

Associate to Bachelor of Science in Clinical Research	$ 15,000 Per Year
Associate to Bachelor of Science in Data Engineering	$ 18,000 Per Year

Master's Programs

Master of Science in Clinical Trial Management	$ 13,500 Per Year
Master of Science in Data Science	$ 13,500 Per Year
Master of Science in Drug Safety and Pharmacovigilance	$ 13,500 Per Year

Certificate Programs

Advanced Clinical Research	$ 4,000
Advanced Drug Safety and Pharmacovigilance	$ 7,500
Advanced Graduate Certificate in Clinical Trial Management	$27,000
Advanced Graduate Certificate in Data Science	$27,000
Advanced Graduate Certificate in Drug Safety and Pharmacovigilance	$27,000
Amazon Web Services	$15,000
Big Data Analytics	$15,000
Big Data Engineering	$15,000
Biostatistics	$15,000
Clinical Data Science	$12,000
Clinical Research and Drug Safety Data Analytics	$27,000
Clinical Trial Management	$ 7, 500
Data Analyst	$ 4,000
Data Science	$15,000
Drug Safety and Pharmacovigilance	$ 4,000
Identity and Access Management	$12,500
Java Full Stack	$15,000
Java Web Development	$15,000
Medical Science Liaison	$15,000
Regulatory Affairs	$15,000
SAS Clinical	$ 4,000
UI/UX Angular	$15,000