phastar

GRADUATE TRAINING PROGRAM

Launch a career in the Clinical Research Industry.

Become a Statistician or SAS Programmer with PHASTAR

Introduction

The Clinical Research industry is bursting at the seams with data and requires talented, skilful statisticians and programmers to organise, prepare, manipulate, and analyse such data. SAS is the industry standard platform used for clinical trials data analysis and reporting for new product submissions to regulatory authorities. SAS is widely recognized as the gold standard for determining safety and efficacy for clinical trials. It is also the primary mechanism for preparing analysis-ready data for traditional clinical research safety and efficacy analysis activities.

At PHASTAR, we have an extensive in-house graduate training program which prepares you to work as a Statistician or Programmer. The combination of instructor-led training/coursework, hands-on learning, mentorship & interaction with programming peers will help you build the foundations of clinical research theory and data manipulation and analysis skills, which can open the door to new opportunities and an amazing career in Clinical Research.

Clinical Trials & Clinical Trial Reporting

Clinical trials are intended to find answers to a research question by means of generating data for supporting or disproving a hypothesis.

The essential characteristic of a clinical trial is that one uses results based on a limited sample of human patients to make inferences about how treatment should be conducted in the general population of patients.

Phases involved in a clinical trial

Phase 1	Phase 2	Phase 3	Phase 4
Phase I trials are the first series of experiments in humans and are primarily concerned with safety, pharmacokinetics, and pharmacodynamics.	Larger scale trials, designed to finalise dose selection and test efficacy for the first time.	Aim to provide definitive assessment of how effective the drug is, in comparison with current 'gold standard' treatment. Usually have strict criteria of success/failure and are multi-centre.	Post-marketing. After a drug has been approved for marketing, it is common to conduct additional studies that will provide further information gathered from long term follow up on a large patient population.
Usually performed in healthy volunteers. Designed to determine acceptable dose.	Performed on the relevant patient population (no healthy volunteers). To decide whether to progress the drug to full phase III program	For marketing approval, it is expected that there be at least two successful Phase III trials, demonstrating a drug's safety and efficacy.	Main interests are adverse events and morbidity/mortality rates, as well as health economics.
Usually between 20 to 80 patients.	Usually between 100 to 200 patients.	Could be into 1000s.	

Introduction to Statistics

Our graduate training program in SAS programming provides the initial framework to progress into a statistical role by providing an understanding of the core competencies related to data analysis and handling. At PHASTAR, we are committed to delivering quality results by ensuring that at every step we are collecting the right data, analysing it the right way, and addressing the questions and objectives set out by the client. Statisticians are key to the planning and execution of clinical trials, and we offer services from the strategic planning of brand new studies, through to the regulatory submission of data to the authorities. We support the client in a huge variety of tasks, including writing Statistical Analysis Plans (SAPs), creating mock shells to show how the table, listing and figure outputs will look, and producing the analyses.

Statisticians work closely with a wide range of experts in different fields. We work closely with data managers through our review of the data collection forms and during the data cleaning process. We work closely with statistical programmers as we provide input and feedback on the dataset specifications, as well as during the creation and review of outputs. We also work with clinicians and medical writers to ensure we understand their needs and requirements throughout the whole process, culminating in submission-ready clinical study reports and publications.

PHASTAR's main product is our expertise. To that end, we are keenly interested in developing our statisticians to the highest level. We have experience in attracting and retaining personnel from across the world, and have a robust onboarding and training program in place which is suited to both office-based and home-based staff. As a graduate, you will experience focused SAS training at the highest level and will be exposed to many different aspects of the clinical trial process whilst under the supervision of an experienced mentor. Beyond the graduate program, we offer plenty of room to grow and develop through regular internal training sessions, mentorship and shadow opportunities. We also encourage staff to attend external training and conference presentations.

Whilst at PHASTAR, you're encouraged to consider your interests and goals on a regular basis so that we can support you in your career development. We have career paths that focus on technical statistics skills, or management, allowing staff to identify and build on their strengths. If you have a Masters-level qualification in Statistics (or higher) and would be interested in a career in clinical trials, please reach out to PHASTAR to find out more information. We'd love to have you onboard!

Introduction to Programming

As programmers, we would typically work on the development of SAS code, that creates analysis datasets, tables, figures, listings (TFLs), and electronic submission packages, to be included in Clinical Summary Reports submissions to the health authorities such as the United States Food and Drug Administration (FDA) and the National Institute for. Health and Care Excellence (NICE). You would also be involved in independent quality control (QC) and validation of peer programmers' statistical datasets, TFLs; as well as meeting milestones, providing functional guidance, and developing operating procedures.

Quality is imperative in clinical trial reporting, as we are working with highly sensitive and confidential data that is used to decide on whether a drug comes to market and is used by the general population. Therefore, it is very important that the programming is 100% correct and providing the right results.

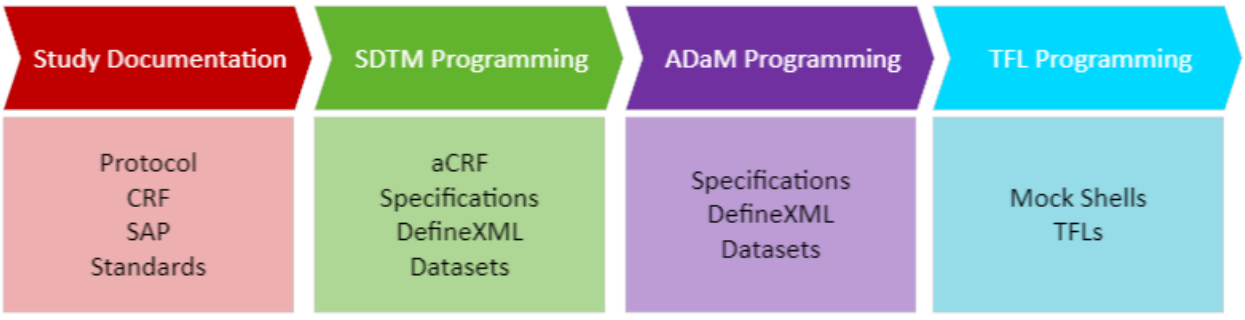
In the majority of cases, clinical trials will follow CDISC standards. CDISC stands for the Clinical Data Interchange Standards Consortium. It is a global not-for-profit organization that develops data standards for the pharmaceutical industry. At PHASTAR, we predominantly work with SDTM and ADaM standards.

SDTM

SDTM stands for "Study Data Tabulation Model." SDTM is arguably the most well-recognized and widely implemented CDISC standard. SDTM outlines a universal standard for how to structure and build content for datasets for individual clinical study data. SDTM data are raw data, and often need further modification before the data are ready for analysis.

ADaM

ADaM stands for "Analysis Data Model." ADaM can also be thought of as data that is "analysis ready." The main difference between ADaM and SDTM standards is the way in which the data is displayed. SDTM provides a standard for the creation and mapping of collected data from raw sources, whereas ADaM provides a standard for the creation of analysis-ready data, often using SDTM data as the source. ADaM datasets can be used by the health authorities to easily recreate analyses.Programmer can work on any, if not all, of the following:



Graduate training course content

Over a five-to-six-week in-house training course you will undergo extensive training in everything from the basics of SAS programming to complex data manipulation techniques, an introduction to clinical trial reporting, industry data standards (CDISC) amongst other topics.

Comprehensive Training

Interactive Learning

Introduction to Clinical Trials

The course contains modules such as:

- SAS Programming essentials, statements, SAS help, Errors and Libraries
- Data step processing, Attributes and Formats
- Selecting Variables/Columns
- Selecting Observations/Rows
- Sorting, Concatenating, Merging and Transposing data
- Accumulating variables and by-group processing
- Loops and Arrays
- Numeric and Character functions
- Macro programming
- Output Delivery System and Reporting
- Tables, listings, and figures development
- SAS Graphics
- CDISC Introduction and Standards
- Validation and quality checking of clinical trial outputs.
  The course will also cover an Introduction to Clinical Trials. Unlike most applications that are programmed by SAS programmers, clinical programming requires a programmer to understand the objective of the clinical trial study, its phases, the study design etc.

Post Training Assessment

Once training is completed, you will complete a short assessment which will help you to ensure that you have understood and mastered the principals that you have learned during your 6 week course.

During your training period, you will also be assigned a line manager and a mentor.
Line managers are there to ensure you are getting the most of out of your training and identify any areas for development or additional training.
Mentors are there to help you technically with any questions or concerns about what you have learnt as part of the training program.

Graduates are also encouraged to meet as a group (whether face to face or remotely) to get to know each other and share any ideas with each other.

Live study work

Once training is completed and the assessment undertaken, you will be put on to live study work. This will be a gradual process, by which you will work closely with your mentors and study teams to become familiar with the working environment and actually study deliverable creation.
After a month or so, you will be a fully pledged Programmer or Statistician and then be responsible for your own project work assignments, programming, and validation of your peer programming (as well as your own), ensuring we are creating the highest quality study outputs that our clients have come to expect.

Career Opportunities and Development

Joining as a graduate is just the start of an exciting and promising career as a Statistician or Programmer at PHASTAR.

As you progress up the ladder, you will take on more responsibilities as both a technical statistician or programmer, team leader and member of the statistics or programming team. From Senior level and above, you are expected to take on the role of lead, whereby they are responsible for the overall production and delivery of all outputs pertaining to the studies they are working on. This involves programming, leadership, monitoring of study progress, resourcing of the study team etc.

All members of the team are encouraged to speak out and make their voice heard, share opinions, put forward ideas for improvement and development and integrate into the wider team and beyond.

Senior Director, Statistics	SD
Director, Statistics	D
Associate Director, Statistics	AD
Statistics Manager	SM
Principal Statistician	PS
Senior Statistician II	SSII
Senior Statistician I	SSI
Statistician III	SIII
Statistician II	SII
Statistician I	SI

Senior Director, Programming	SD
Director, Programming	D
Associate Director, Programming	AD
Programming Manager	PM
Principal Programmer	PR
Senior Programmer II	SII
Senior Programmer I	SI
Programmer III	PIII
Programmer II	PII
Programmer I (Graduate)	PI

The PHASTAR discipline

Last but by no means least is the PHASTAR discipline.

At PHASTAR, we pride ourselves on doing things differently. All staff should follow a set of tried and trusted 'golden rules' which ensure that we are producing consistent high-quality work. This is important because we want to ensure that as a company and as individuals, our reputation is the best in the industry.

The discipline consists of four main areas which have underlying rules to follow.

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