



A Programmer's journey to enhance knowledge & expertise

**PHUSE Education:
Therapeutic Areas and
Clinical Document**

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PHUSE Education



The vision of PHUSE Education is to create a PHUSE roadmap to education, which covers the broad bandwidth of knowledge a clinical data scientist needs to have to be successful in their job.



This covers both hard and soft skills, as well as technological understanding and, most importantly, a thorough domain understanding.



For more information, or if you would like to get involved, contact education@phuse.global.

PHUSE Education

The different streams



Regulatory Environment

This educational section will provide clarity on the regulatory process from the data scientist's perspective. It is important to recognise that data scientists should not only have a thorough understanding of the submitted data but should also be familiar with how they are consumed by our regulatory authorities. The Regulatory Framework will aim to summarise the key inflection points with regulators, provide an understanding of how regulatory bodies use submitted data to support drug approval and provide intelligence on emerging approaches that could influence the way clinical trial data is submitted in the near future.



Drug Development

This educational cluster focuses on aspects of drug development in the pharma industry. Drug development in commercial biopharma may be divided into three sequential domains:

- Pre-clinical – using in vitro and in vivo data
- Clinical drug programme development (CLINICAL) – using in-human data
- Postmarketing using Real-World Data (RWD) and Real-World Evidence (RWE) data



Technology & Applications

This cluster will address educational needs of PHUSE members in the Technology & Applications space. PHUSE was founded as an organisation with a focus on technology and application users and promoting collaboration amongst contributors. There are many and varied drivers influencing our choice and usage of technology and applications, and this section will focus on identifying, categorising and educating/informing users about the choices available.



Job Skills

This educational section will provide curated educational resources around a broad skillset that encompasses job skills. These skills have been broken into a limited set of categories that can be useful throughout your career. Some of the skills will also relate to other clusters in the Education area of PHUSE.



Programming Languages

Programming Languages are an integral component of data science within the context of the pharmaceutical industry. Their use is varied, and they can, for example, be used to provide analytics from data collected from real-world evidence, clinical and nonclinical trials, to assess the efficacy and safety of drugs and/or devices (e.g. inhalers) in trials.



Data Engineering

The Data Engineering Cluster will explore how established data engineering techniques successfully deployed in other industries could be utilised in our industry. From traditional data warehousing to the arrival of the big data lake, with data marketplaces, ePRO and IoT, the challenge is on to identify analytical value from all these disparate data sources.



Industry Standards

This educational section will provide curated educational resources, as it relates to standards within the industry regarding the data we capture, clean and analyse in the biopharma industry.



Data Science

Data science describes a cross-functional field which uses scientific methods to extract knowledge from data.

Techniques from disciplines like mathematics and statistics, computational and information science are utilised to generate hypotheses and draw conclusions based on various data sources.

Source: [PHUSE Education](#)



Therapeutic Areas

Therapeutic Area (TA) expertise becomes more and more important for clinical data scientists working in the pharmaceutical industry as it is crucial for the understanding of patients' needs and the interpretation of analysed data.

For a profound knowledge of a TA, the following information is of critical importance for the clinical data scientist:

- Description of Disease
- Demographics and Baseline Characteristics
- CDISC Standards and Therapeutic Area User Guides
- Agency Guidelines
- Study Design and Study Endpoints
- Data Challenges



Clinical Documents

Clinical Documents build the foundation of the clinical drug development process. Various regulations control the scope and nature of essential documents. At times, the number of different documents, their purpose and relevance for the various stakeholders can get overwhelming. The PHUSE Education cluster on Clinical Documents aims to provide insight into the available clinical documents and to put emphasis on those of particular interest for the PHUSE Society.

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- Content
- Authors, Reviewers, Approvers and Target Audience
- Timelines
- Maintenance / Amendments
- Dependencies
- Supportive Documents
- Underlying Guidelines
- References

Source: link [here](#)

PHUSE Education

Clinical Documents and Therapeutic Areas

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Ask colleagues?
Difficult during pressure-
filled delivery timelines.
Easy to get intimidated.

Web search?
Results may not always be
focused or accurate.

Company trainings?
Are usually role- &
department- specific. Hard
to find if tied to SOPs or
training systems.



The **Clinical Documents** cluster aims to provide insight into essential documents used during the clinical drug development process.

The **Therapeutic Areas** cluster aims to provide thorough overviews of disease descriptions, study designs, data challenges and underlying guidelines.

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For more
information or to
join the group



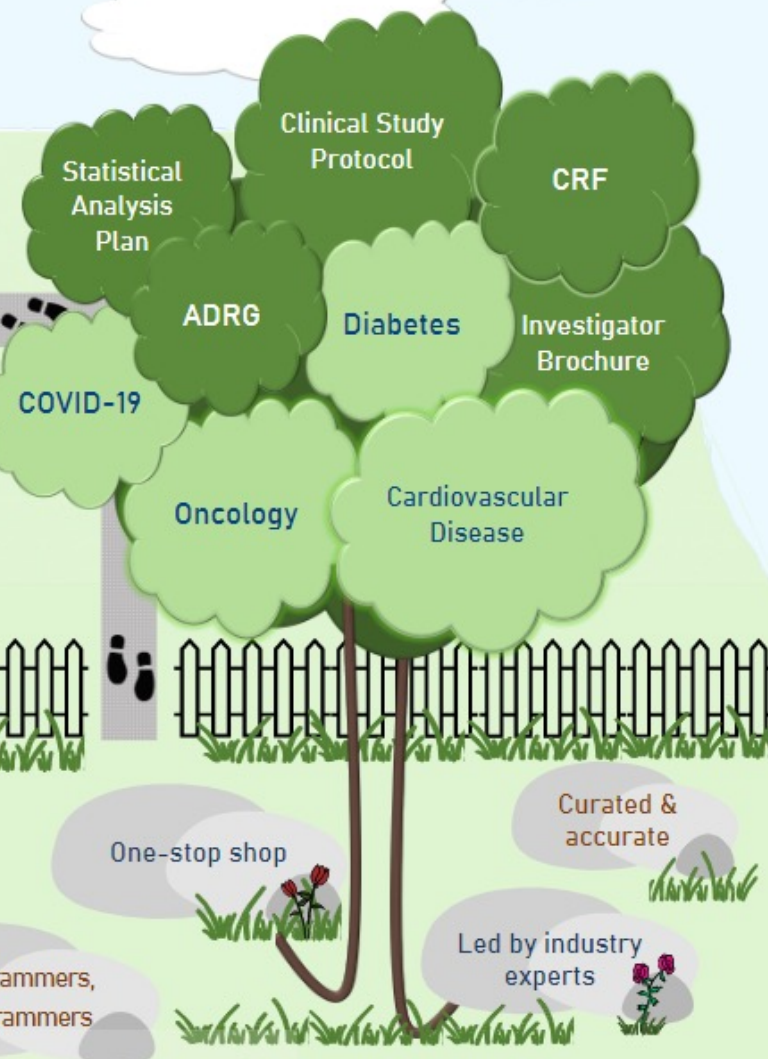
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Clinical Documents

Therapeutic Areas



By programmers,
for programmers

Curated &
accurate

Led by industry
experts