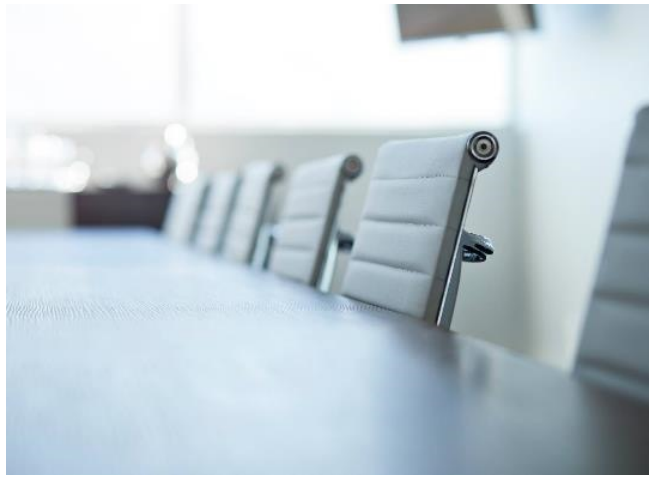
PHUSE Education Overview

Aron Wisneski

Bristol Myers Squibb™



Corporate Ambitions

(Vision, Priorities, & Objectives)

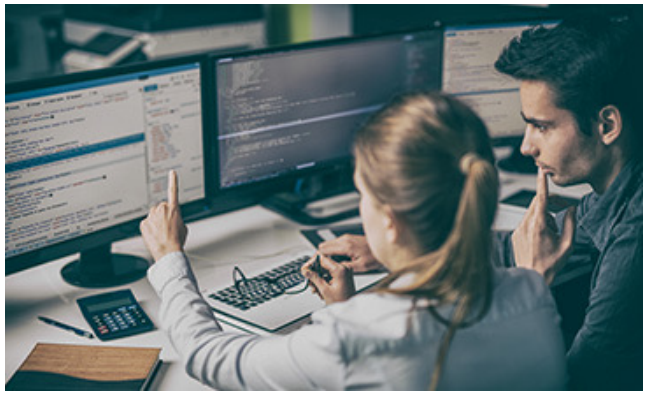
Develop **industry-leading reputation** through enhanced external partnerships

Grow and evolve our **talent** to expand impact

pharmaceutical users software exchange (https://phuse.global)

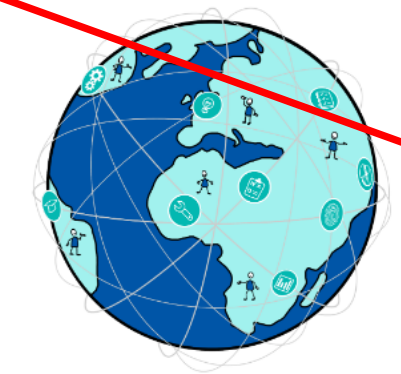
Who We Are and What We Do:

PHUSE is an independent, not-for-profit organization run by a worldwide team of volunteers. We are a global community and platform for the discussion of topics encompassing the work of data managers, biostatisticians, **statistical programmers**, data scientists and eClinical IT professionals. PHUSE has become the industry voice to regulatory agencies and standards organizations such as the FDA, EMA & CDISC.



The Global Healthcare Data Science Community

Sharing ideas, tools and standards around data, statistical and reporting technologies



About PHUSE

New to PHUSE? Find out more about who we are and what we do, and get involved!

Find Out More

Deliverables

View the Working Group deliverables including white papers, references and regulatory referenced documents.

Search the Deliverables

PHUSE Open Data Repository

The PODR platform will help individual users to acquire new skills to improve their job prospects.

Learn more

Job Vacancies

If you are looking for a new opportunity or want to advertise a vacancy, use our jobs board.

Find Opportunities

Volunteer with PHUSE

Actively participate in the Working Groups, join an event committee, present at an event or try your hand at writing an article!

Join Us

PHUSE Archive

Access PHUSE materials from previous Connects, Single Day Events, Webinars and publications.

Search the Archive

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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.

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.

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

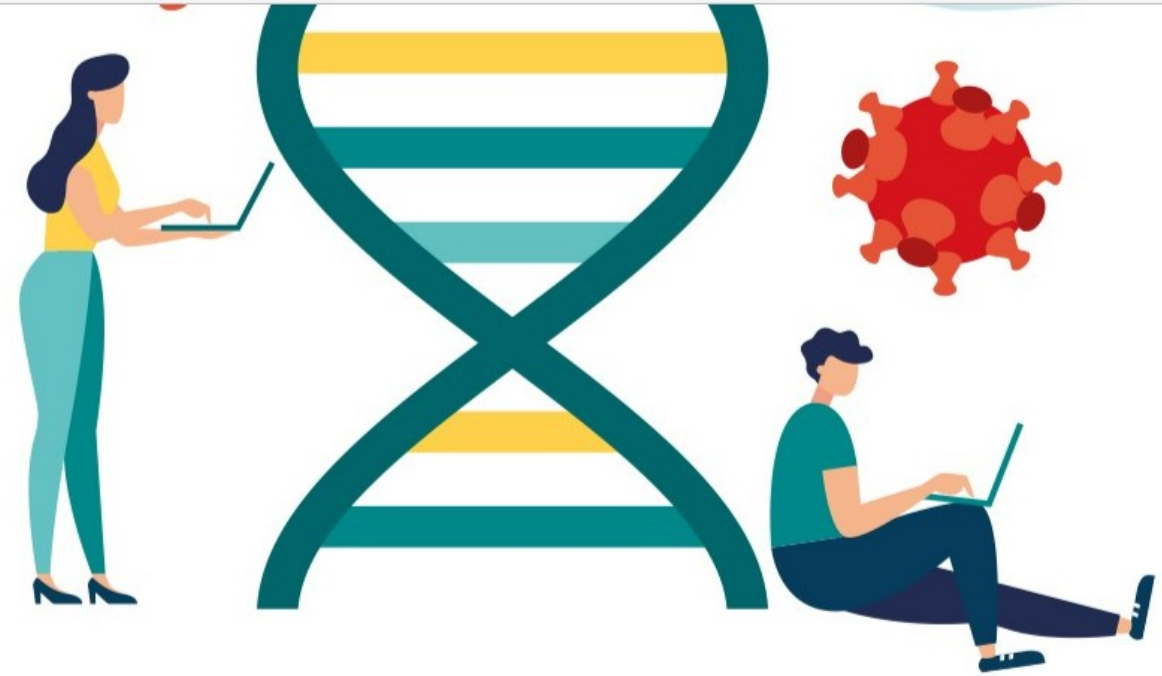
Drug Development

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

TA & CD Committee:

Beate Hientzsch
Alberto Montironi
Rabia Ahmad
Amar Mahidadia
Adrian Czaban
Zuzana Rehm
Stine Dalmann Ross
Aron Wisneski



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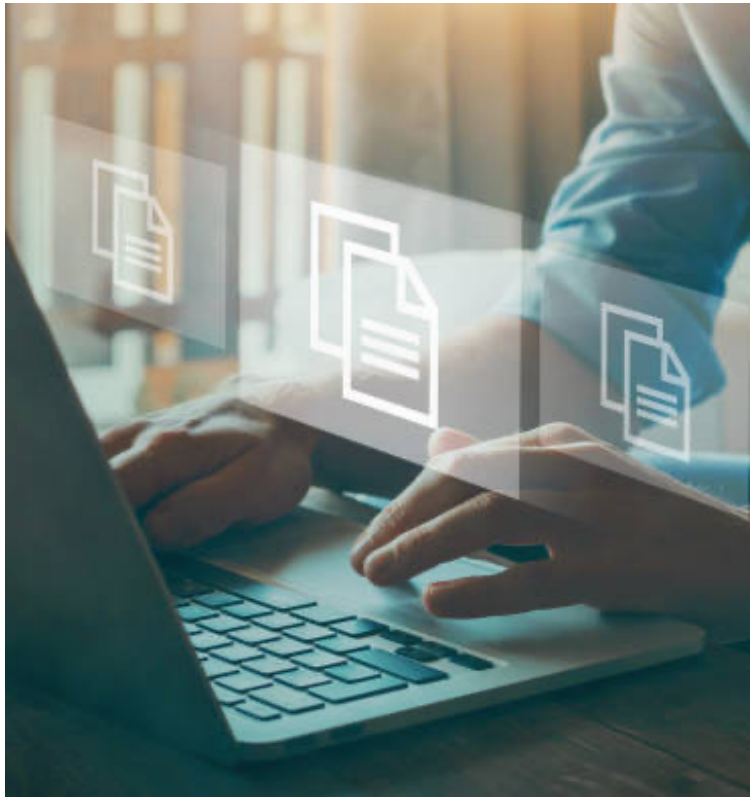
Our PHUSE Educations teams is working on comprehensive overviews for various Therapeutic Areas, which are referenced below.

Each comprehensive TA overview follows the structure as described below.



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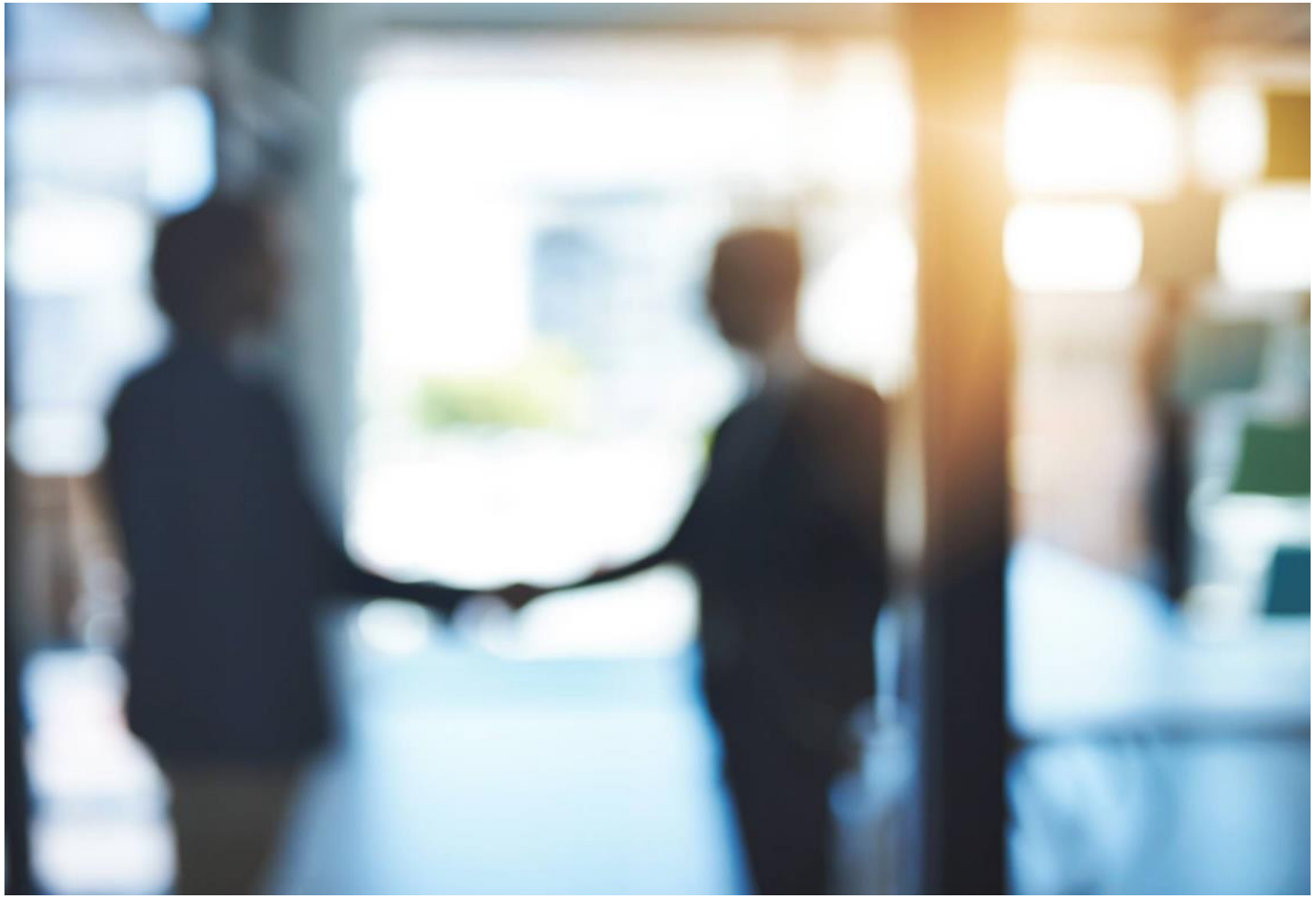
1. Each of us ***writes*** our first draft of an item.
2. We ***share*** with the group to review before our bi-weekly meetings.
3. Online meeting to ***discuss***, ***edit***, and ***improve***.

Benefits

1. Company Engagement

2. Industry-wide Impact

3. Collegiality & Camaraderie



Thank you

Aron Wisneski

Senior Manager – Statistical Programing

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