

Data Sciences Project

Educating for the Future Working Group

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Agenda

- Working Group Background
- How we started...
- Biopharma Data Sciences
- Foundation: Data and Biostatistics CDS
- Next Steps

Working Group Background

- PHUSE CSS 2018: Foundation of Educating for the Future WG
- Goal: Develop and distribute framework to educate PHUSE community on topics, where we feel we have gaps



Home Educating for the Future Standard Scripts



PHUSE Mission

PHUSE is an independent, not-for-profit organisation run by volunteers. A society with a membership exceeding 8,000, across more than 30 countries worldwide, PHUSE has become the industry voice to regulatory agencies and standards organisations such as the FDA, EMA & CDISC.

We act as a global platform for the discussion of topics encompassing the work of data managers, biostatisticians, clinical data scientists and eClinical IT professionals.



2018 Tokyo Single Day Event

The goal is to develop and distribute frameworks by which to educate the PHUSE community at large. The frameworks will be designed to inform the community on the importance of topics where we feel we have gaps, the details of the topics themselves, and how they can be used to drive

Education Mission



Working Groups

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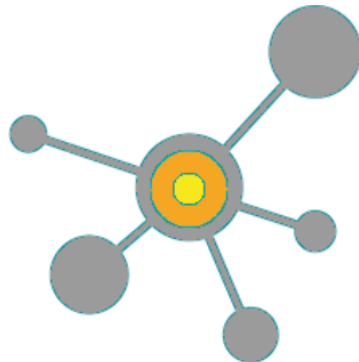
Working Group Background

Educating for the Future Projects



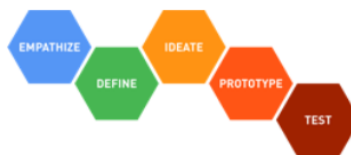
Data Sciences

Drawing conclusions of various (big) data sources



Data Engineering

Taking a holistic view of data representation and usage



Design Thinking

Innovation through creative problem solving and group ideation

<http://education.phuse.eu>



Home Educating for the Future Standard Scripts



PHUSE Education

Welcome to the PHUSE education content repository

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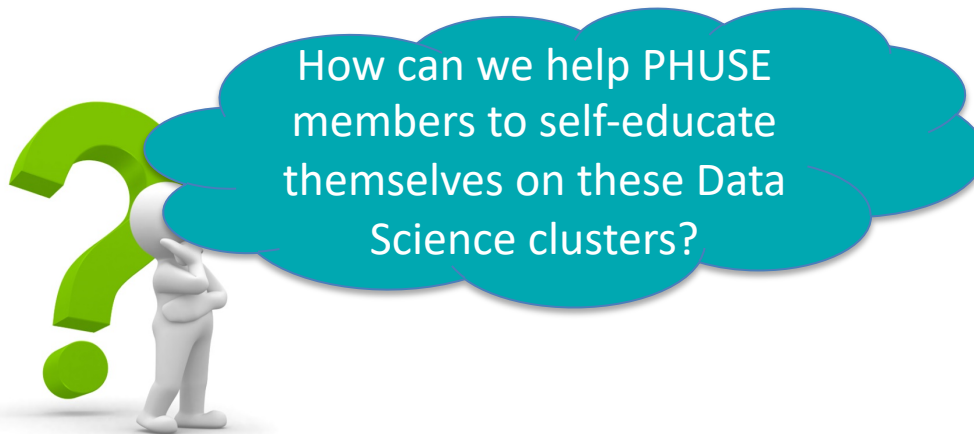
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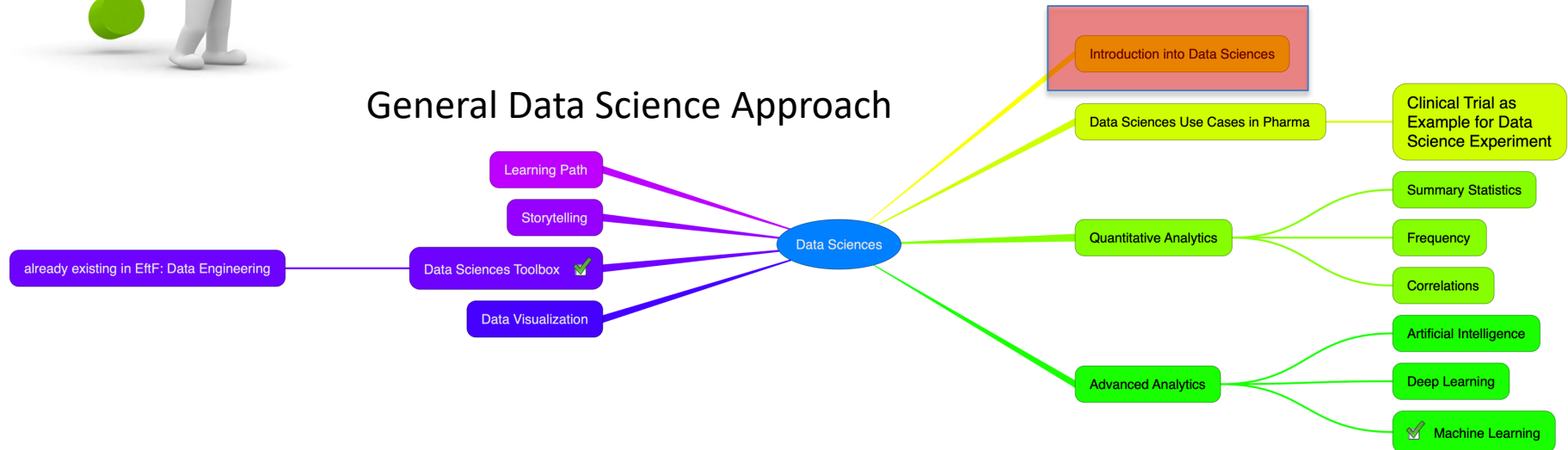
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How we started...



Huge challenge due to diverse background and different understanding of Data Science vs. Data Scientist

General Data Science Approach

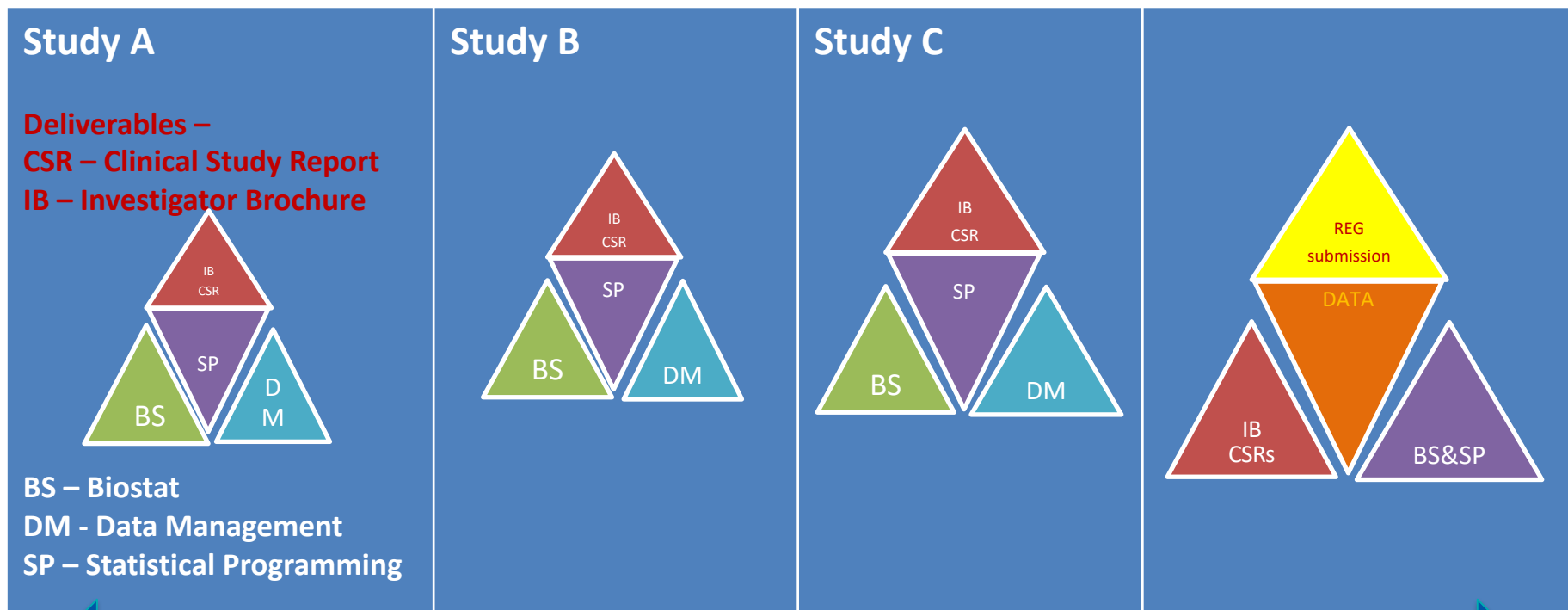


Biopharma Domains

Commercial BIOPHARMA		
R&D – EXPERIMENTAL “EXPLORATORY” or “CONFIRMATORY” Long term evidence collection Prospective, gold standard RCT		“OBSERVATIONAL” “Rapid” Analysis of Real-Time Data mix observational, prospective, retrospective
Pre-Clinical	Clinical Development	Post-Registration, Pharmacovigilance/Post Market Surveillance
	Phase I to Phase III Clinical trials	“Phase IV” clinical trials, Real-World Data Real World Evidence
	Medical, Regulatory Clinical Operations, BIOMETRICS Pharmacovigilance, ...	Pharmacovigilance, Medical Affairs ^[1] , Marketing, Business Development

Biopharma Classical Biometric stakeholders

Clinical Trial – linear – SOP bonded



Biopharma Clinical Development Data Scientist



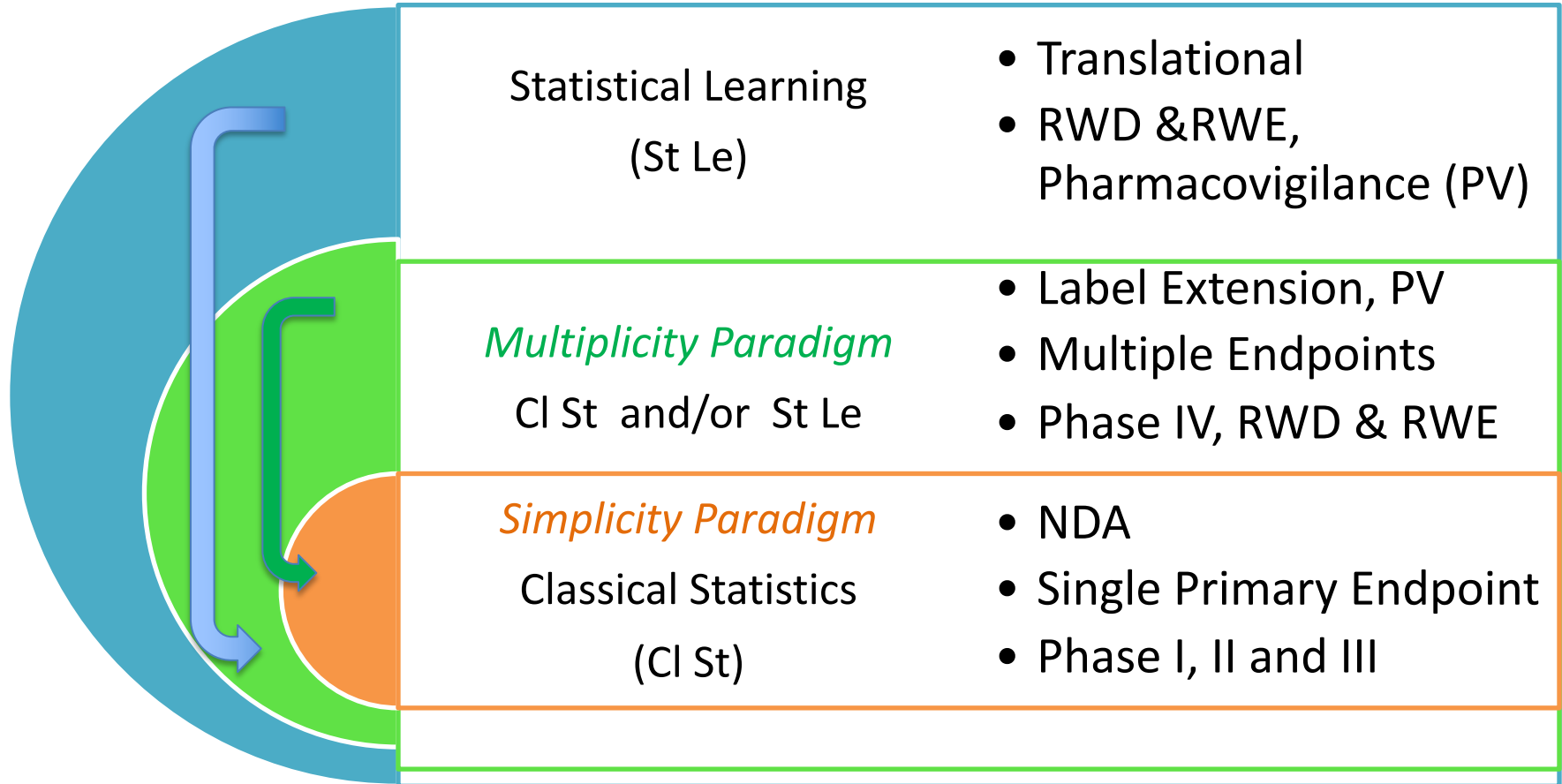
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Definition: Clinical Data Scientist

- inherently an **integrative discipline**
- ensures well planned traceable data collection, harmonized optimization, integration, analysis and display of different data sources throughout the clinical drug program development
- reduces uncertainty and creates knowledge



Foundation: Data and Biostatistics CDS



Fundamental Concepts

CDS overarching planning of clinical drug development design articulates around :

Reproducibility — *consistent results using same data, computational steps, methods and conditions of analysis*

Replicability — *consistent results across studies aimed at answering the same scientific question, each of which has obtained its own data*

Generalizability — *the extent that results of a study apply in other contexts or populations that differ from the original one*

CDS Examples

Clinical Experiments meet real-life

One Brave Idea — *research initiative gathering real-world digital phenotypes to identify CHD far before it escalates to be life threatening*

GSK's Salford Lung Study *large, prospective, real-world COPD trial combining robust scientific methods used in RCTs with benefits of observing real patients in real settings.*

Digital Biomarkers — *new data sources offer new opportunities to translate new data sources into informative, actionable insights*

Real World Evidence — *SA03 on JNJ using RWE as supporting data during FDA NDA technical walkthrough*



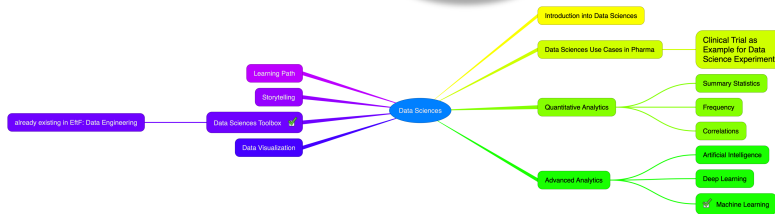
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Next Steps

We have PHUSE members on different levels...How can they enter the education path?

It all starts with Statistics! How can we educate Analytical Thinking?



Create general Learning Path based on a use case approach following examples from Pharma Clinical Development

- Start with simple use cases and examples and become more complex
- Within each use case tackle as many clusters
- Use the PPDAC Approach and Six Divisions of Greater Data Sciences to explain examples to help learning analytical thinking

Create focused Learning Path for various roles within Pharma

- Where should a programmer start?
- Where should a software developer start?
- ...

Conclusion

- **Pharma data requires an intimate domain understanding**
- **CDS overarching role beyond classical biometrical functions**
- **Biostatistics is foundation of Clinical Data Science**
- **Requires continuous self education supported by PHUSE**



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ACKNOWLEDGEMENTS

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