

Emerging Trends and Technologies And Educating for the Future

Tokyo SDE

Ian Fleming

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Emerging Trends & Technologies



**Computational Science
Working Groups**



New Co-leads

Andy Richardson (d-Wise)
Zhijun (Stanley) Wei (Novartis)



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ET&T Current Projects

- Clinical Trials Data as RDF
- Blockchain in Clinical Trials
- Clinical Program Design as RDF
- Cloud Adoption
- Data Visualization
- ODM4Submission
- Research on FHIR
- Key Performance Indicators



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Clinical Trials Data as RDF

- **Project Overview**

Evaluate new ways of representing trial data and looking at insights gained. Includes round-tripping data (XPT to Linked Data, Linked data to STDM, data lineage, etc)

- **Current Status**

Ontology development well advanced. Talking with OBO Foundry about hosting. Presenting at US Connect.



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Blockchain in Clinical Trials

- **Project Overview**

Investigate the use of Blockchain in Clinical Trials through examination of the technology and evaluation of Use Cases.

- **Current Status**

Whitepaper soon to be released for Review.
Presented at multiple international conferences/forums. Presenting at US Connect



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Clinical Program Design as RDF

- **Project Overview**

Develop an ontology for the representation of a Clinical Program.

- **Current Status**

Developed an ontology and set of relevant Concept Maps (CMAP) describing the domain. On pause awaiting technical input with Ontology implementation.



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Cloud Adoption

- **Project Overview**

Work to develop a framework that can accelerate the adoption of Cloud Technology in BioPharma.

- **Current Status**

Published framework and socialized with the wider industry (operational and regulatory). Working towards updating Framework for next release. Looking at targets, messaging, accessibility.



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Data Visualisation

- **Project Overview**

Look at how effective data visualization approaches can accelerate the development of insights in clinical studies.

Partitioned into 3 sub-teams

- Best Practices for Interactive Analyses for Decision-making & Submissions
- Use of Data Visualizations for Subject Level Data Review
- Use of Data Visualizations for Data Anomaly Detection)

Each team working towards deliverables.

Collaborations being developed (FDA, Transcelerate, etc)



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ODM 4 Submission

- **Project Overview**

This project explores how the existing ODM standard could simplify and modernize data exchange in support of regulatory submission requirements (eg. as a replacement for the aged XPT)

- **Current Status**

Currently in start-up; recently published at the CDISC EU Interchange. Looking for volunteers



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Research on FHIR

- **Project Overview**

Evaluation of the use of HL7 FHIR as a API-led approach to the acquisition, integration and management of Healthcare data for Clinical Research.

- **Current Status**

Phase I complete (DM TA sourced from EHR).

Whitepaper in development, sample application used to demonstrate concepts and illustrate use cases.

Presenting at US Connect.



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Educating for the Future



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Current Co-Leads



Ian Fleming
Medidata Solutions



Geoff Low
Medidata Solutions



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Working Group Mission

- The goal of this Working Group is to develop frameworks by which to educate the PhUSE community at large. The frameworks will be designed to educate 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 innovation in the industry.

Co-Leads



Ian Fleming
Medidata Solutions



Jim McDermott
Achieve Intelligence



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Data Engineering

- This project will explore how established Data Engineering techniques, successfully deployed in other industries, could be utilized 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 of these disparate data sources.
- Co-leads
 - Guy Garrett, Achieve Intelligence
 - Bev Hayes, Johnson and Johnson



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Machine Learning and Artificial Intelligence

- Our goal is first to introduce ML & AI to the pharmaceutical industry. These concepts are foreign to most programmers and statisticians in the pharmaceutical industry. This project will help them to start ML & AI through educational materials. Secondly we will explore how ML & AI can foster innovative approaches in data-driven research and drug development, personalized medicines, faster drug discovery and more.
- Co-leads
 - Nicolas Dupuis, Novartis
 - Kevin Lee, Clindata Insight



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Design Thinking

- By definition, DT is 'a formal method for practical, creative resolution of problems and creation of solutions'. DT methods foster a way of thinking that reframes the problems and solutions we assume we have the answer to. It also puts heavy emphasis on experimentation, iteration, and user feedback to quickly develop solutions that derive maximum benefit for end users and the actual problems they are trying to resolve.
- Co-leads
 - Crystal Allard, FDA
 - Ian Fleming, Medidata Solutions



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March 2018 CSS

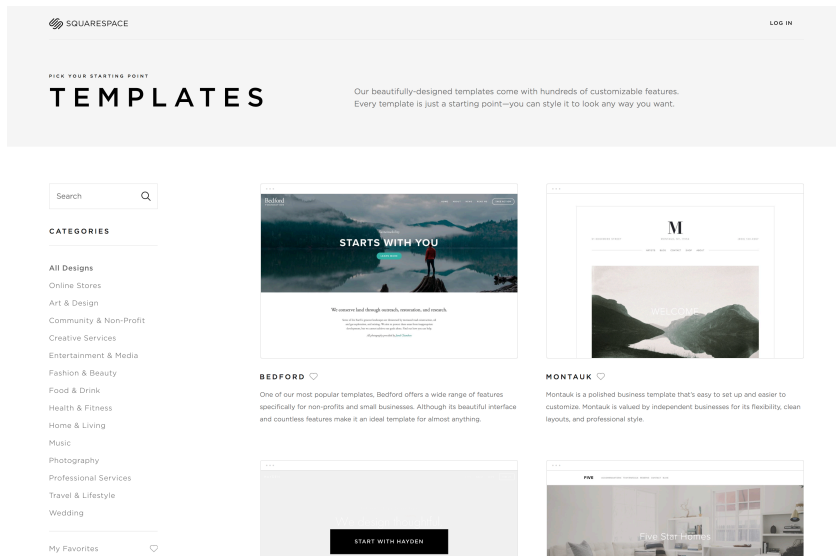
After introducing the WG and individual projects, the members who attended the CSS session this year discussed collective needs, and agreed to a set of user/system requirements (at a high level) for our desired approach.

- User friendly
- Usage metrics analytics
- Many users & types
- Configurable



Education Repository

Squarespace has been chosen as the tool to host the PhUSE EftF repository. It is a software as a service-based content management system, integrated website builder, and blogging platform.



- High level navigation and design is currently being built out
- Projects will begin populating content within the next few months

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