
Emerging Trends and Technologies – An Update

Emerging Trends and Technologies



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Alternative Transports Format

- The paper is done (well mostly)
- Will be submitted to the PhUSE Steering Committee in the next week
- There will be no Phase II – response rate was too low to suggest this is a problem that needs solving with incentives (carrots)
- We need a stronger imperatives to motivate any substantive change (sticks)



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Update from Cloud Adoption Working Group

- Barriers in process of being re-examined:
 - cost models
 - security concerns
 - knowledge & education
 - organizational
- Identified next WG deliverables:
 - Updated whitepaper, v4 – **on hold for now**
 - New supplementary document, “what if scenarios” – **sub-team underway**
 - New instructional document(s), “how to adopt” – **underway**
 - More evangelizing initiatives
- FDA deliverable review process for the cloud WG whitepaper; looking for a champion – tabled for May PhUSE meeting
- Asking PhUSE to approach FDA Commissioner’s office re. draft guidance on cloud computing



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Use Cases for Data Visualizations

Group 1

- **Best Practices for Interactive Analyses for Decision-making & Submissions**
- Ongoing Aggregated Safety
- Signal Detection
- Registries & Rare Diseases
- help w ad hoc requests
- Traceability
- Efficacy/QC visualizations

Group 2

- **Use of Data Visualizations for Subject Level Data Review**
- Patient Narratives
- Patient Progress
- Patient Profiles
- Efficacy Viz for Analyses
- Viz for QC & Analysis & Reporting
- Traceability of TLF/G
- RWD/RWE

Group 3

- **Use of Data Visualizations for Data Anomaly Detection**
- Data Quality
- Anomaly Detection
- Data Cleaning
- Metrics & Operational Performance
- Central Monitoring
- Signal Detection
- Registries & Rare Diseases
- RWD/RWE

Group 4

- **Use of Data Visualizations for Study Level Data Review**
- Methods and Tools for Study Narratives
- Annual Safety Report
- Drug Safety Update Report



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Evaluating the Use of FHIR in Clinical Research

Research on  FHIR

Emerging Trends and Technologies



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The Project Thus Far

- The group will use [Mitre's SyntheticMass](#) EHR database and pull Diabetes data listed in the CDISC Diabetes Therapeutic Area User Guide (TAUG);
- We will extract the Demography, Diabetes Type, most relevant Lab parameters, and Cardiovascular Events & Outcomes to create SDTM datasets;
- Our deliverables will include an annotated CRF with both the SDTM and [FHIR Resource](#), where possible;
- The ultimate goal of the team is to determine if the data available in FHIR Resources can be used in clinical trial submissions.



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Background

Actual EHR data are notoriously dirty and not easily usable in the more structured submission data environment. The SyntheticMass database, Synthea, is synthetic EHR data generated by Mitre, a not-for-profit based in Boston. Synthea holds EHR data representative of the state of Massachusetts, capturing everything a real patient would experience from birth to death in certain Therapeutic Areas. The data are freely available on GitHub.

The Diabetes TAUG provides detailed examples for many of the data needed for a Diabetes submission. We will concentrate on a small portion of the data due to timing.



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Shameless plug

We want anyone interested and is willing to do some work to join us.

This is brand new territory and, we gotta admit, a little exciting.

Please contact Trisha Simpson or Chrissy Johnson if you have any questions.



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Research on FHIR



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Educating for the Future

- A new working group intended to formulate topics and methodologies intended to help educate the PhUSE community on trends and technologies that are occurring outside our industry
- Examples
 - Data Science, ML/AI, Design Thinking and User focused development, Hyper Agile Software Development and Deployment
- What's next:
 - Kicking off the working group
 - Finalize project scope and how we work with other WGs
 - Picking the initial topic areas (3-4)
 - Choose topic leads
 - Develop education plans for selected topic areas



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