Feedback from the EBF - The historical discussions (OS 2018/2019) and interactions with software developers

Cecilia Arfvidsson, on behalf of the EBF
Data Integrity – Continued regulatory focus

WHO and OECD Draft Guidelines in 2019 and 2020

“Data governance and data integrity (DI) are important elements in ensuring the reliability of data and information obtained in production and control of pharmaceutical products. The data and information should be complete as well as …. meeting “ALCOA” principles.”

“In recent years, the number of observations made regarding the integrity of data, documentation and record management practices during inspections … has been increasing. Possible causes for this may include (i) too much reliance on human practices; (ii) the use of computerized systems that are not appropriately managed and validated; and (iii) failure to adequately review and manage original data and records.”
Data Integrity and EBF

- MHRA ‘GXP’ Data Integrity Guidance issued in March 2018.

- EBF workshop arranged at the OS 2018 in collaboration with the MHRA

- To provide insight and understanding of regulatory data integrity expectations – focus on data integrity and audit trails

- Outcome - Open up the dialogue for enhanced interaction between software developers, pharma/CROs and regulatory authorities to understand current, and define future, system Data Integrity capabilities¹.

E-environment Workshop at EBF OS 2019 - Building Common Understanding for Future System Solutions

- Highlight **current key DI challenges**, focusing on the data transfers in the **LC/MS workflows**
- What are the **missing functionalities** in today's process?
- What can the **software developers** do to help improve the current situation?
E-environment Workshop at EBF OS 2019 - Building Common Understanding for Future System Solutions

- The “interface landscape” is often the key issue for most bioanalytical labs and workflows when it comes to DI.

- EBF focus - a joint mission to resolve the current interface and secure data transfer issues.

- WS a successful first step towards a consensus and an increased dialogue between the software developers and the bioanalytical community.

- Outcome - two clear and concrete messages:
  - From the BioA community – the software developers need to explain what they require from the BioA community to “make it happen”.
  - From the software developers - the BioA community needs to agree on a joint request for the software developers to focus their efforts.
Continuous dialogue with the software developers

- **Long-term solution** not available in the next few years
  - Secure transfer of the **complete data set**
  - **File-less transfer** using a vendor neutral interface

- **Customized solutions** available - time and cost expensive

- EBF acts only in the **non-competitive space** for the benefit of the entire BioA community
  - An advantage in the identification of a **limited** but **sustainable solution**

- Stepwise approach to **break the current status quo** and to showcase that progress can be made if/when all agree on a common standard
EBF proposal for a generic data transfer

- Focus on the data used for integration purpose in the bi-directional data transfers between information management (IM) system and LC/MS

- Using only a minimum data set, strictly required to safeguard DI

- The minimum data set agreed by the EBF environment team and presented for the EBF core community in May 2020

- Published on-line Bioanalysis in July 2020

Generic fields in the transfer from IM to LC/MS system

**Run/File-specific**
- Study / Project
- Run / Batch file
- User (GLP)
- Plate Barcode
- File Name

**Sample-specific**
- Sample name/ID
- Sample barcode/ID
- Analyte (s)/ Internal Standard name
- Dilution factor
- Order Number
- Plate Position
- Sample type
- Concentration
Generic fields in the transfer from LC/MS to IM system

**Run/File-specific**
- Study
- Run
- Date/Time
- User
- Plate Barcode
- File Name
- User Comments

**Sample-specific**
- Sample name/ID
- Sample barcode/ID
- Analyte (s)/ Internal Standard name
- Analyte raw data (peak area, height, ratio…)
- Analyte (s) conc data
- Dilution factor
- Plate position
EBF engagement and scope

- Every BioA lab has its own workflows - complexity of the data format to be transferred easily accelerates.

- The EBF e-environment team has tried to come as close as possible when building the generic list for the software developers to work on.

- Important to move this forward as a community - likely some additional internal harmonization needed to prevent from creating new ambiguity to the software developers as the journey continues.

- EBF will not propose further technical details. It’s now with the software developers to work with their customers to develop these solutions.

- Early adaptors can hopefully be used as an example for others to then follow.
Software developer engagement

- All software developers in **agreement** - the time and cost required to have a technical solution ready for implementation is low – **this is not complex** so let’s get it done!

**Diagram:**
- Understanding the scope
- EBF Data transfer specification (with clarifications)
- Vendor data sets
- Final data model
- Hackathon and pilot implementation
Future perspective - towards the long-term DI solution

- Current data transfer proposal - an inspiration to facilitate additional steps?
  - additional platforms
  - all data
  - long-term storage and archiving
  - file-less interface solution

- Multiple questions and challenges to be addressed and resolved as the complexity increase
  - How to handle the outputs from the different plate-readers (>1 wavelength, replicates on the same sample, blank subtraction …)?
  - How to define rules for exceptions (negative/text/empty values …)?

A continuous engagement and dialogue between all relevant parties is critical to reach further progress
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- EBF core community
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