15th Open Symposium

The Bioanalytical Compass

Navigating to our True North

Past, current and future of the EBF discussions, challenges and recommendations on secure data transfer

Cecilia Arfvidsson, on behalf of the EBF

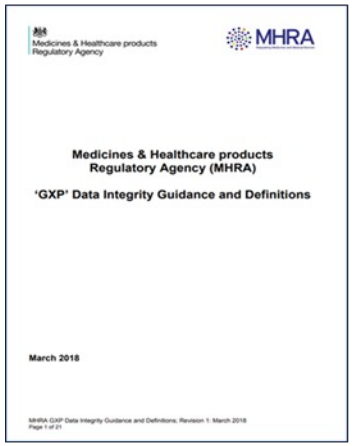
16-18 November 2022, Barcelona

Presentation outline

- EBF and the strategic focus on Data Integrity challenges
- A secure data transfer process
  - vendor neutral LC/MS prototype work
  - deep dive into the LBA platforms
- Finger on the Pulse (FotP) survey on implementation of a vendor neutral interface in LC/MS workflows
- Continued discussions during this EBF Open Symposium

High regulatory focus on Data Integrity

Multiple guidelines with a Data Integrity focus have been issued and sent out for consultation the last few years.


Medicines & Healthcare products Regulatory Agency

MHRA

Medicines & Healthcare products Regulatory Agency (MHRA)

'GXP' Data Integrity Guidance and Definitions

March 2018

MHRA GXP Data Integrity Guidance and Definitions; Revision 1: March 2018
Page 1 of 21

MHRA issued in 2018


OECD

Organisation for Economic Co-operation and Development

ENV/CBC/MONO(2021)26

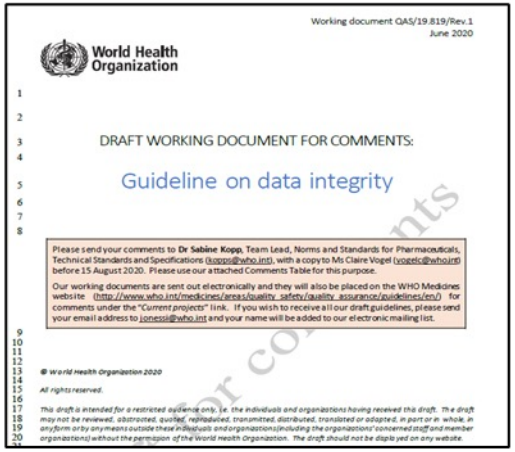
Unclassified — English - Or. English — 20 September 2021

ENVIRONMENT DIRECTORATE
CHEMICALS AND BIOTECHNOLOGY COMMITTEE

OECD SERIES ON PRINCIPLES OF GOOD LABORATORY PRACTICE AND COMPLIANCE MONITORING

Number 22
Advisory Document of the Working Party on Good Laboratory Practice on GLP Data Integrity

OECD issued in 2021


Working document QAS/19.819/Rev.1
June 2020

World Health Organization

DRAFT WORKING DOCUMENT FOR COMMENTS:

Guideline on data integrity

Please send your comments to Dr Sabine Kopp, Team Lead, Norms and Standards for Pharmaceuticals, Technical Standards and Specifications (kopps@who.int), with a copy to Ms Claire Vogel (vogelc@who.int) before 15 August 2020. Please use our attached Comments Table for this purpose.

Our working documents are sent out electronically and they will also be placed on the WHO Medicines website (http://www.who.int/medicines/areas/quality_safety/quality_assurance/guidelines/en/) for comments under the "Current projects" link. If you wish to receive all our draft guidelines, please send your email address to jonessi@who.int and your name will be added to our electronic mailing list.

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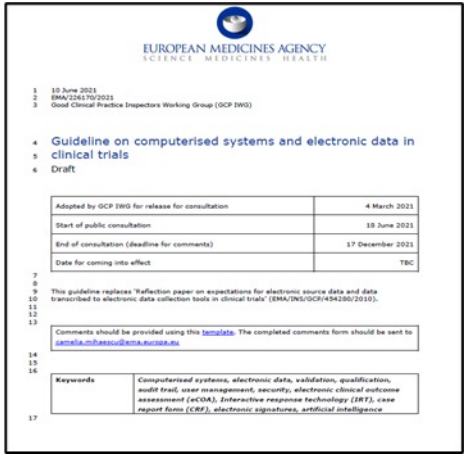
WHO draft for consultation (2020)


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 June 2021
EMA/226170/2021
Good Clinical Practice Inspectors Working Group (GCP IWG)

Guideline on computerised systems and electronic data in clinical trials
Draft

Adopted by GCP IWG for release for consultation	4 March 2021
Start of public consultation	10 June 2021
End of consultation (deadline for comments)	17 December 2021
Date for coming into effect	TBC

This guideline replaces 'Reflection paper on expectations for electronic source data and data transcribed to electronic data collection tools in clinical trials' (EMA/INS/GCP/454280/2010).

Comments should be provided using this template. The completed comments form should be sent to camelia.mihaescu@ema.europa.eu

Keywords	Computerised systems, electronic data, validation, qualification, audit trail, user management, security, electronic clinical outcome assessment (eCOA), interactive response technology (IRT), case report forms (CRF), electronic signatures, artificial intelligence

EMA draft for consultation (2021)

Final guidelines

Draft guidelines

Historical EBF discussions

EBF has a long history of discussing e-data and data integrity challenges:

- 2012 ELN workshop
- 2013 Workshop: defining raw data in regulated bioanalysis
- 2014 Workshop on e-Data: towards a common standard
- 2015 Workshop: generic data transfer agreement
- 2015 Session: Going paperless
- 2016 Discussion on Harmonised implementation of OECD17
- 2016 Session: e-Environment
- 2017 Workshop: Approaches on implementing OECD17
- 2018 Session: e-Environment
- 2018 Workshop: Data integrity with contributions from the MHRA
- 2019 Workshop: Building Common Understanding for Future System Solutions
- 2020 Workshop: Towards a vendor neutral secure bi-directional data transfer process
- 2021 Sessions: Data (F2F) and Data Integrity and e-data (cyber)

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 e-environment team and presented for the EBF core community in May 2020
- Published on-line Bioanalysis in July 2020[1]


White Paper

For reprint orders, please contact: reprints@future-science.com

Improving data integrity in regulated bioanalysis: proposal for a generic data transfer process for LC–MS from the European Bioanalysis Forum

Bioanalysis

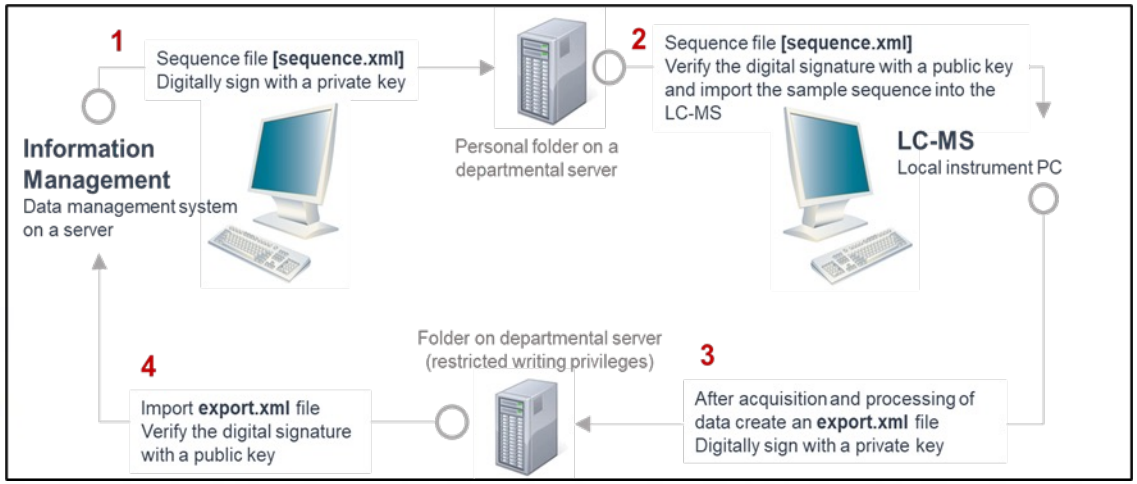
[1]Arfvidsson C, Van Bedaf D, Globig S *et al*. Improving data integrity in regulated bioanalysis: proposal for a generic data transfer process for LC–MS from the European Bioanalysis Forum. *Bioanalysis* 12(14), 1033-1038 (2020).

Vendor neutral data transfer solution

A secure, vendor neutral data transfer model was presented by a team of software developers / instrument vendors at the EBF OS in Nov 2020.

Proposal

Worklist/result information is transferred as a vendor neutral XML file format. The proposed data model is flexible and scales beyond LC-MS workflows.



Replacing .txt files with digitally signed .xml files

Improved data security

The need for any manual and time-consuming quality-control steps to mitigate the DI risks is removed by signing the XML file with a digital signature

What have happened since?

EBF e-environment team

Deep dive into the LBA workflows

Mapping exercises

Establish channels for continued dialogue and communication

Interdisciplinary vendor working group

Build an awareness & understanding

Collect feedback

Evaluate interest in vendor & lab community

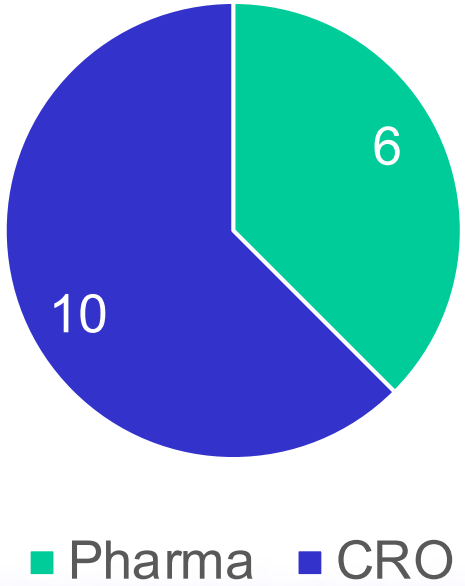
A vendor voice on the vendor neutral data transfer prototype

“In this initiative, the second e-environment focused workshop arranged at the 12th EBF OS in 2019, was a positive driver to engage regulators and bioanalytical laboratories to agree on the DI ‘problem’. The White Paper published in Bioanalysis 2020 was also a positive vehicle to define the scope of a future solution. However, finding regulatory bioanalytical laboratories in pharma or CRO environments willing to step forward and consider ‘change’ was a significant barrier to the product time-line and as a result developing a case to make it happen was less than straightforward”

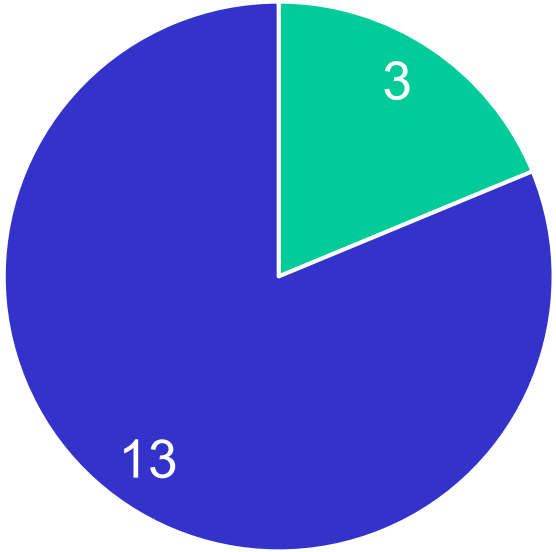
EBF Finger on the Pulse Survey

- A Finger on the Pulse Survey was sent out in preparation for this EBF OS
  - To investigate how the vendor neutral data transfer prototype has been received by the BioA community
  - To collect feedback on the interest in as well as any hurdles for implementation

16 core members responded to the FotP survey

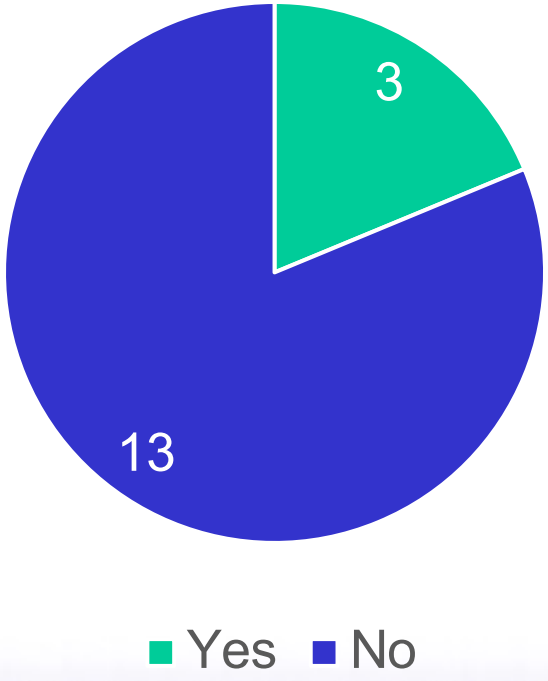


Have you / your lab been involved in any work to have the secure vendor neutral data transfer prototype implemented in your LC/MS workflow?



<20% of responding (<5% of all?) EBF core members have been involved in any prototype implementation work

Have you/ your lab engaged with any of your vendors to discuss possible future implementation of the secure vendor neutral data transfer prototype?



<20% of responding (<5% of all?) EBF core members have engaged with a vendor to discussion potential future prototype implementation

If not, why so?

No Priority

Digital interfaces already in place which covers most of the workflow

It's a great idea but we just haven't really considered

No capacity to test prototypes

No requests from sponsors

Due to challenges in engagement with internal stakeholders (IT)

We plan to discuss this with our vendors end of this year

Not working with LC/MS, with LBAs, secure data transfer from reader to LIMS via protected file manager software and file folders

We are at the early stages of getting a LIMS system, and the available software may be adequate for our needs.

A lab voice on the vendor neutral data transfer prototype

“When I heard the vendor working group’s talk at the EBF OS in 2021 I was really intrigued that we could really get some improvements going in this important direction. I immediately vouched for our lab to be part of the testing community and we were quite willing to spend time on this. However, I had to learn that again people were ping-ponging the responsibility …and said something to me like “you are the only one asking for it”. I simply heard it was not on the priority list for upgrading and basically they said “there is no solution available”. Which was totally contrary to what was said and implied to at the EBF meeting.”

In Summary

- A true vendor neutral application for the bi-directional data transfers between the information management and the LC-MS system has been developed and is undergoing the product pathway
- The EBF e-environment team's focus for 2021 and 2022 has been a deep dive into the LBA platforms that could benefit from similar exercises and interaction with software developers for improve DI
- Based on the FotP survey implementation of the vendor neutral data transfer prototype is slow
- Based on lab and vendor voices EBF's goal to release some frustration with regards to data transfer and DI has not (yet) been achieved

To consider …for the panel discussion

- **The challenge** - translating what may appear to be a ‘good idea’ into a true business need, fully supported by the bioanalytical community.

- **The challenge** - translating what may appear to be a ‘good idea’ into a true vendor priority, fully supported by vendor upper management.

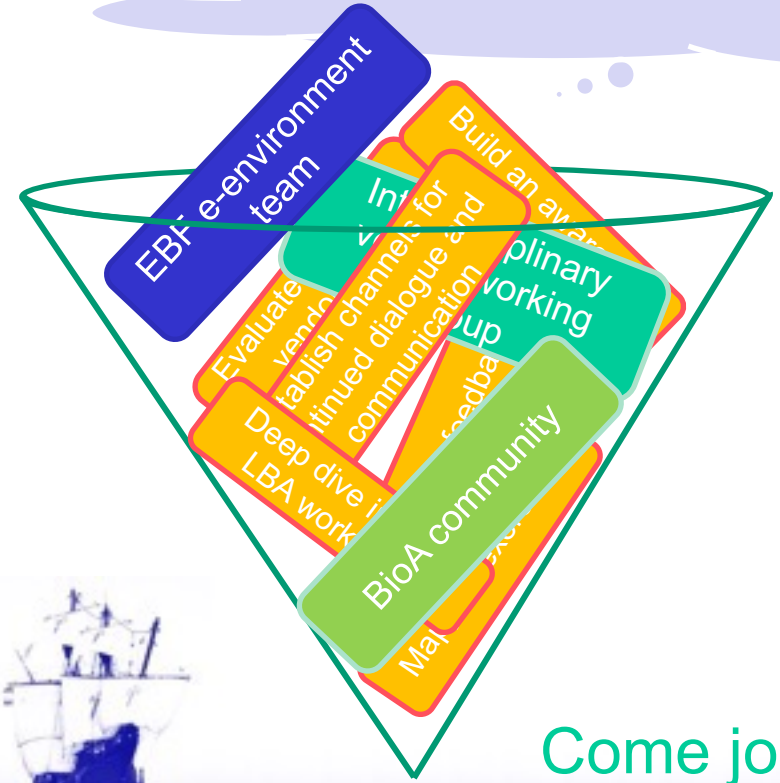
? How should we move forward with the roll out of the LC/MS prototype?

? How to best take any future initiatives forward?

? What can we learn from these experiences?

E-environment workshop – Pier 2 EBF OS Day 2

The cloud



- Focus on our day-to-day challenges with regards to DI
- Desired outputs:
  - knowledge sharing
  - an increased awareness/understanding around some of our common challenges with regards to data integrity
  - having a mutual understanding of what we need/what our challenges are and if/where EBF can facilitate

Come join the discussion!!

Acknowledgements

- EBF e-environment team
- EBF core community
- Interdisciplinary vendor working group

Contact Information

Questions: info@e-b-f.eu

European Bioanalysis Forum vzw
www.e-b-f.eu