14th EBF Open Symposium (Cyber Meeting)

Science – Our Universal Language

Status update on EBF e-environment team progress (Chromatography & LBA tools)

Cecilia Arfvidsson, on behalf of the EBF

1-3 December 2021, Cyber meeting

Presentation Outline

1. *EBF and Data Integrity*
2. *A brief update on the LC/MS prototype work*
3. *An introduction to the EBF e-environment LBA team & the new focus*
4. *FotP survey on Key DI topics*
5. *Next steps*

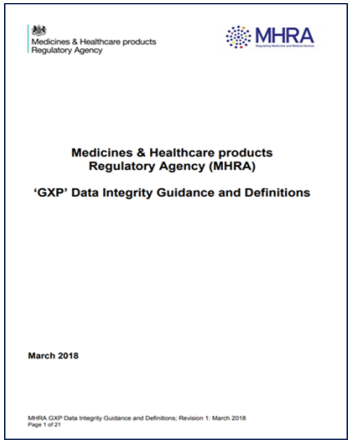
Historical EBF e-Environment themes

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

Increased 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

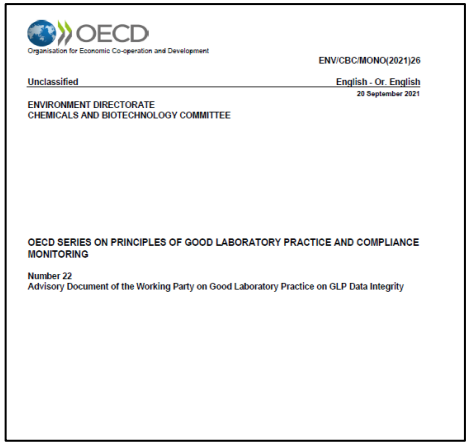
MHRA

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


OECD

Organisation for Economic Co-operation and Development

ENV/CBC/MONO(2021)26

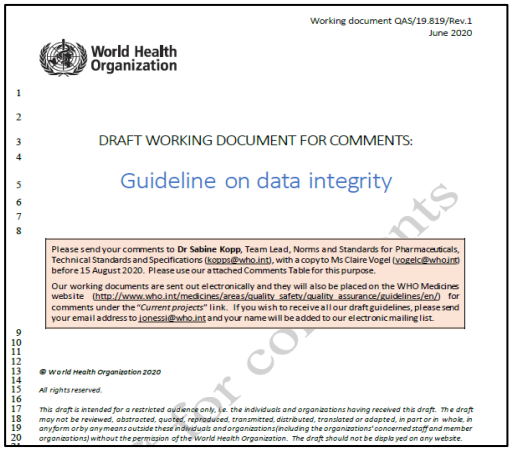
Unclassified — English - Or. English

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


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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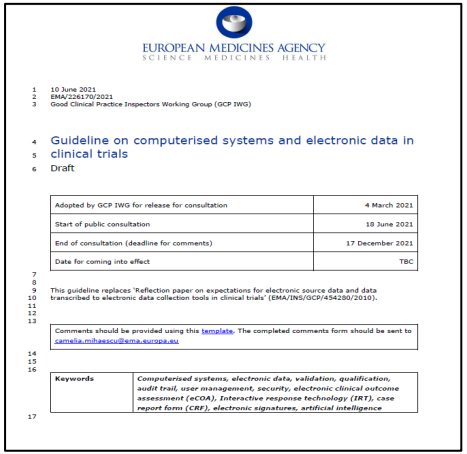

EUROPEAN MEDICINES AGENCY
SCIENCE · MEDICINES · HEALTH

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	18 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 form (CRF), electronic signatures, artificial intelligence*

Final guidelines

MHRA issued in 2018

OECD issued in 2021

Draft guidelines

WHO draft for consultation (2020)

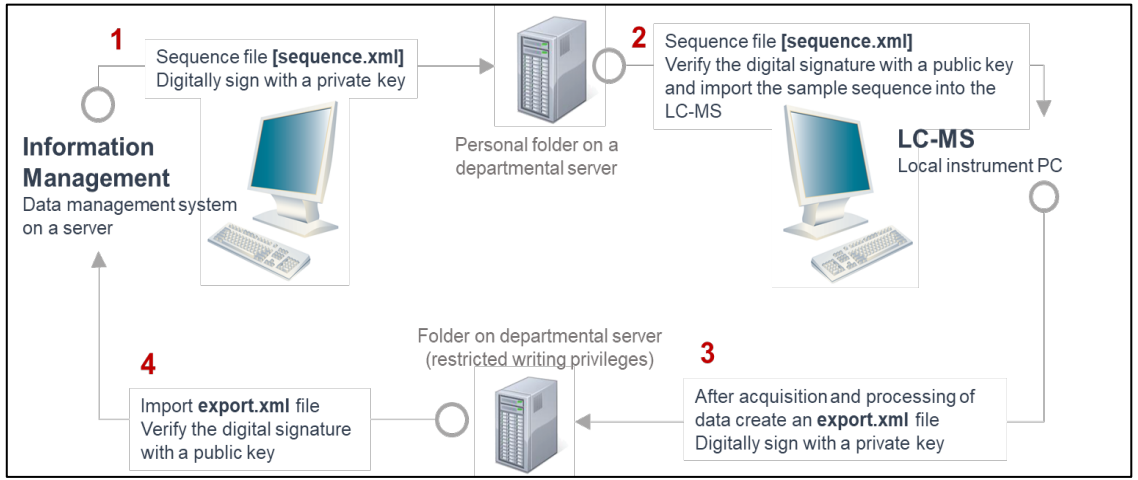
EMA draft for consultation (2021)

Vendor neutral data transfer solution (LC/MS)

. 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**

EBF

SOLUTION
- Data transfer model prototype

Build an awareness & understanding

Collect feedback

Evaluate interest in vendor & lab community

- Are we on the right track?
- Anything we've missed?

- This is no rocket science

IMPLEMENTATION
- In an authentic lab environment

- Is there enough interest to go from prototype to implementation?
- Are there any early adopters?
- Any additional vendors to come aboard?

EBF e-environment team focus 2021 – the LBA workflows

Aim: to use the knowledge and experience from the LC/MS DI work to proactively investigate if **additional platforms** could benefit from a similar exercise and interaction with software developers to **identify any DI gaps and increase DI**.

How: A deep dive into the LBA workflows

- Identify LBA platforms at risk
  - *Which platforms may not meet health authorities' data integrity expectations?*
- Map out the LBA workflows
  - *Are there any common DI gaps?*
  - *What additional complexity to consider?*
  - *Can a common standard be agreed?*
- Map out the key software/instrument vendors
  - *to initiate the dialogue around current gaps and possible solutions*

Data Integrity feedback exercise

Aim: Summarise **positive and constructive DI feedback** on the most commonly used instrumentations and software to facilitate in a future constructive and relevant **dialogue** with the **individual software developers** and **instrument vendors**;

- MSD Discovery Workbench (MSD)
- GyroLab platforms (Gyros Protein Technologies)
- SoftmaxPro (Molecular Devices)
- Magellan (Tecan)
- Watson LIMS (ThermoFisher)

How: The key aspects of data integrity has been considered:

- Data transfers between systems
- User access levels
- Audit trails
- Archiving of study data

Form the basis for a **'wish list'** and to building the **'ideal system'** from a DI perspective.

In the ’ideal’ instrumentation/software there’s ….

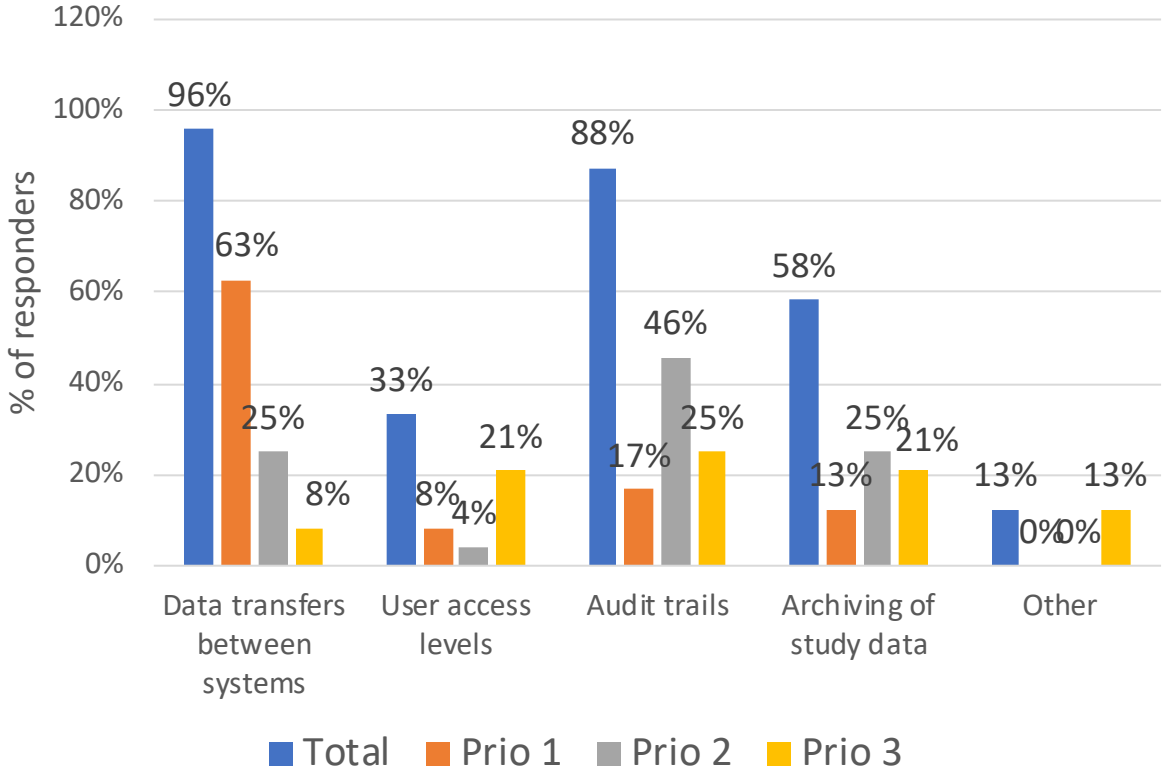
- **Data storage and transfer**
  - Data transfer in a secure file format
  - A direct interface to and from LIMS or at least a “standard output format” that can be used as a template for any LIMS
  - Flexibility within database to be able to select what files to export
  - Possibility to export and re-import raw data into database
  - Database for file storage
- **User access levels**
  - Built-in application account
  - Lock options at several stages
  - Data and user management within a database
- **Audit Trail**
  - Full audit trail available and within a database (not file based)
  - A more extensive system audit trail filter
- **Archiving of study data**
  - An opportunity to archive individual parts of the database

EBF Finger on the Pulse Survey on DI

Aim: to collect **feedback from the EBF core community** to ensure that the key DI topics, identified by the team, is representative for the entire BioA/LBA community.

No of responders to the FotP survey = 24

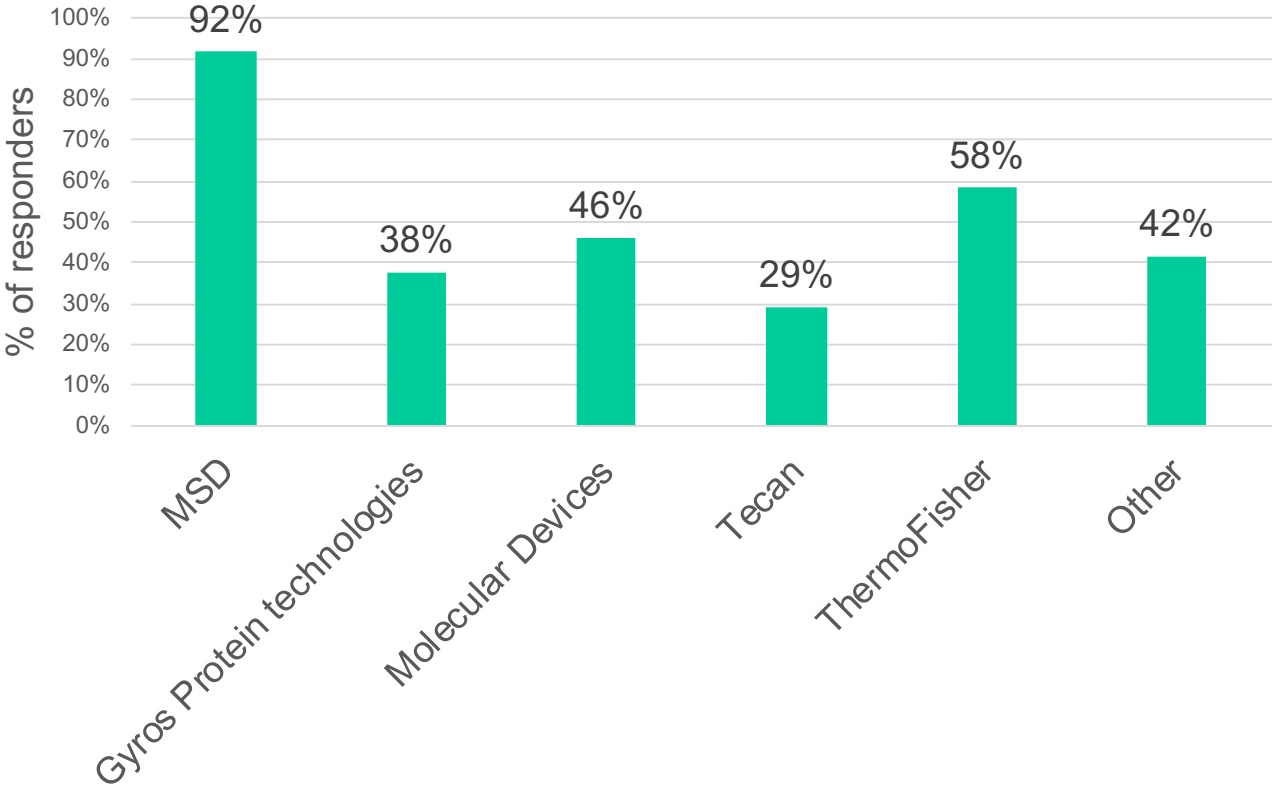
Q1. Which of the following topics do you see as a key priority from a LBA Data Integrity perspective



Other being:

- Cloud services and vendor portals
- DI for immunogenicity data

Q2. Which of the following LBA software developers /instrument vendors would you like to see participate in a discussion around the Data Integrity challenges in the LBA workflows



Other being:

- Quanterix (Simoa)
- LabWare (LIMS)
- LabVantage (LIMS)
- Sapio (LIMS)

FotP survey in summary

- The EBF **core community is well aligned with the EBF e-environment team** on the key priority Data Integrity topics in the LBA workflow
  - **Prio 1** – Data transfers between systems
  - **Prio 2** – Audit trails
  - **Prio 3** - Archiving of study data

- The key LBA software developers/instrument vendors, identified by the team for further engagement and discussions were also confirmed by the EBF core community
  - MSD
  - Thermo Fisher and other LIMS vendors (such as LabVantage, Labware, Sapio)

EBF e-environment team welcome all vendors into the planned future dialogue

Next steps

- Identify the 'channels' for **continued communication** and **dialogue**

- Initiate the dialogue with instrument and software vendors to **facilitate in new, improved DI features** in the LBA workflows
  - In line with the regulatory expectations
  - Minimising manual and time consuming quality controls
  - Identify any low hanging fruit for improved data integrity

- Identify **similarities and differences** in the LC/MS vs. LBA workflow challenges
  - Learnings from LC/MS that can be applied also for LBA

Acknowledgements

- EBF e-Environment team
  - Mark Lewis (GSK)
  - David Van Bedaf (Janssen)
  - Susanne Globig (Idorsia)
  - Chris Jones (AstraZeneca)
  - Jens Sigh (NovoNordisk)
  - Yvan Verlinden (Janssen R&D)
  - Milan Vagaday (Celerion)
  - Karl Pettersson (Ferring)
  - Martina Reis-Dybowski (Roche)
  - Harm Buddiger (Genmab)
  - Katja Zeiser (Nuvisan)
  - Ranbir Mannu (Labcorp)
- Software developers and Instrument vendors
- EBF core community

Thank you for your attention!

- Any questions?

Contact Information

Questions: info@e-b-f.eu

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