EBF

14th EBF Open Symposium

Science – Our Universal Language

Updates on Data integrity requirements in (emerging/draft/new) regulatory Guidelines

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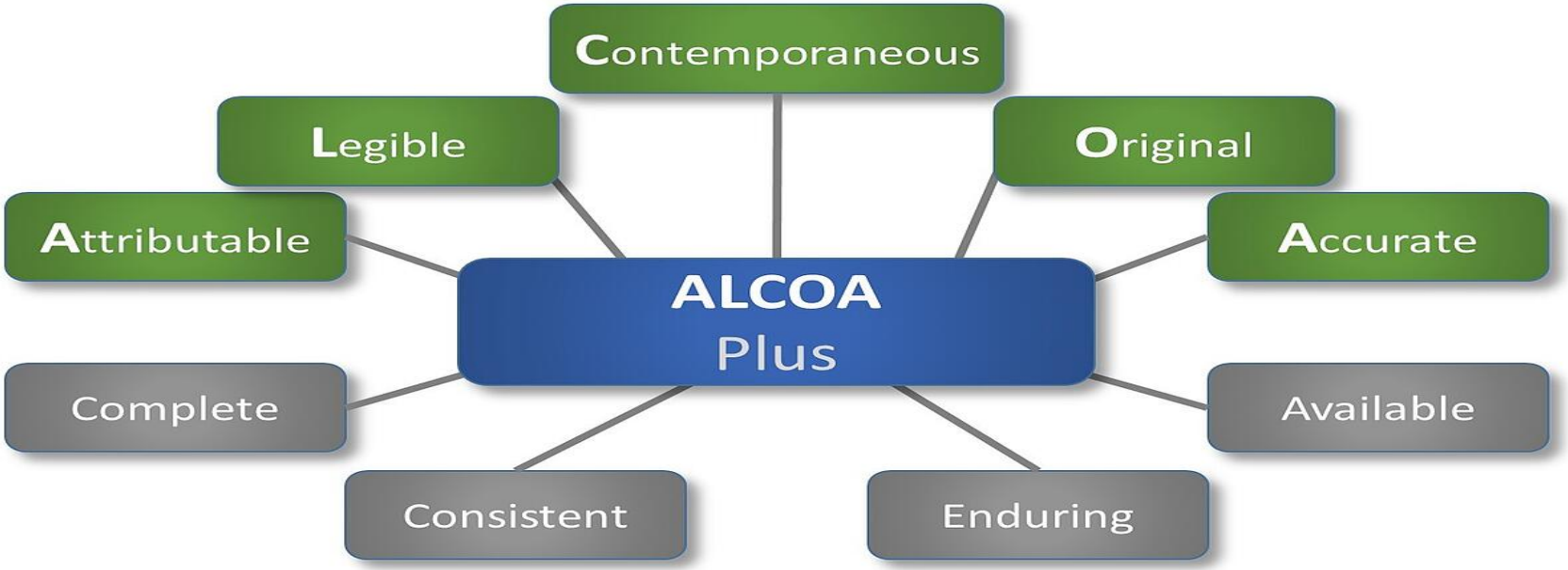
02 December 2021, Cyberspace

Good Old Data Integrity

- Data integrity has always been central to what we do



Regulatory Horizon

- MHRA ‘GXP’ Data Integrity Guidance and Definitions, issued in March 2018
- OECD No 22, Advisory Document of the Working Party on Good Laboratory Practice on GLP Data Integrity, issued in Sept 2021
- WHO Revision 1 draft guideline on Data Integrity, sent out for consultation June 2020 (to replace WHO Annex 5)
- EMA draft guideline on computerized systems and electronic data in clinical trials, sent out for consultation in June 2021

Looking close at the guidelines

MHRA ‘GXP’ Data Integrity Guidance and Definitions

- Scope: GxP
- Paper are electronic documents are concerned
- Data Life Cycle requirements presented
- DI integrity risk assessment is expected

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

- Scope: GLP
- Paper are electronic documents are concerned
- Data Life Cycle requirements presented
- Clear expectation about responsibilities in terms of DI
- DI integrity risk assessment is expected

WHO Revision 1 draft guideline on Data Integrity

- Scope: GxP
- Paper are electronic documents are concerned
- DI integrity risk assessment is expected

EMA draft guideline on computerized systems and electronic data in clinical trials

- Scope: GCP
- Electronic records are concerned
- Data Life Cycle requirements presented
- DI integrity risk assessment is expected
- Particular requirements on CSV

EMA draft guideline on computerized systems and electronic data in clinical trials

- Scope

The scope of this guideline is computerised systems, (including instruments, software and services) used in clinical trials in the creation/capture of electronic clinical data and to the control of other processes in the conduct of a clinical trial of investigational medicinal products. These include, but may not be limited to the following:

To summarize

	MHRA	OECD 22	WHO	EMA
Scope	GxP	GLP	GxP	GCP
Paper or electronic	Both	Both	Both	Electronic
Data Life Cycle requirements	Yes	Yes	No	Yes
Responsibilities	No	Yes	Yes	Yes
CSV	No (only access and roles requirements)	No (only access and roles requirements)	Yes	Yes
Risk-based approach	Yes (formal requirement for DI risk assessment)	Yes (formal requirement for DI risk assessment)	Yes (formal requirement for DI risk assessment)	Yes


Arigato
Mahalo
Grazie
Spasiba
THANK YOU
Thoinks Moite
Gracias
Merci
Danke
Shukran

Acknowledgements

- Cecilia Arfvidsson
- EBF Community

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