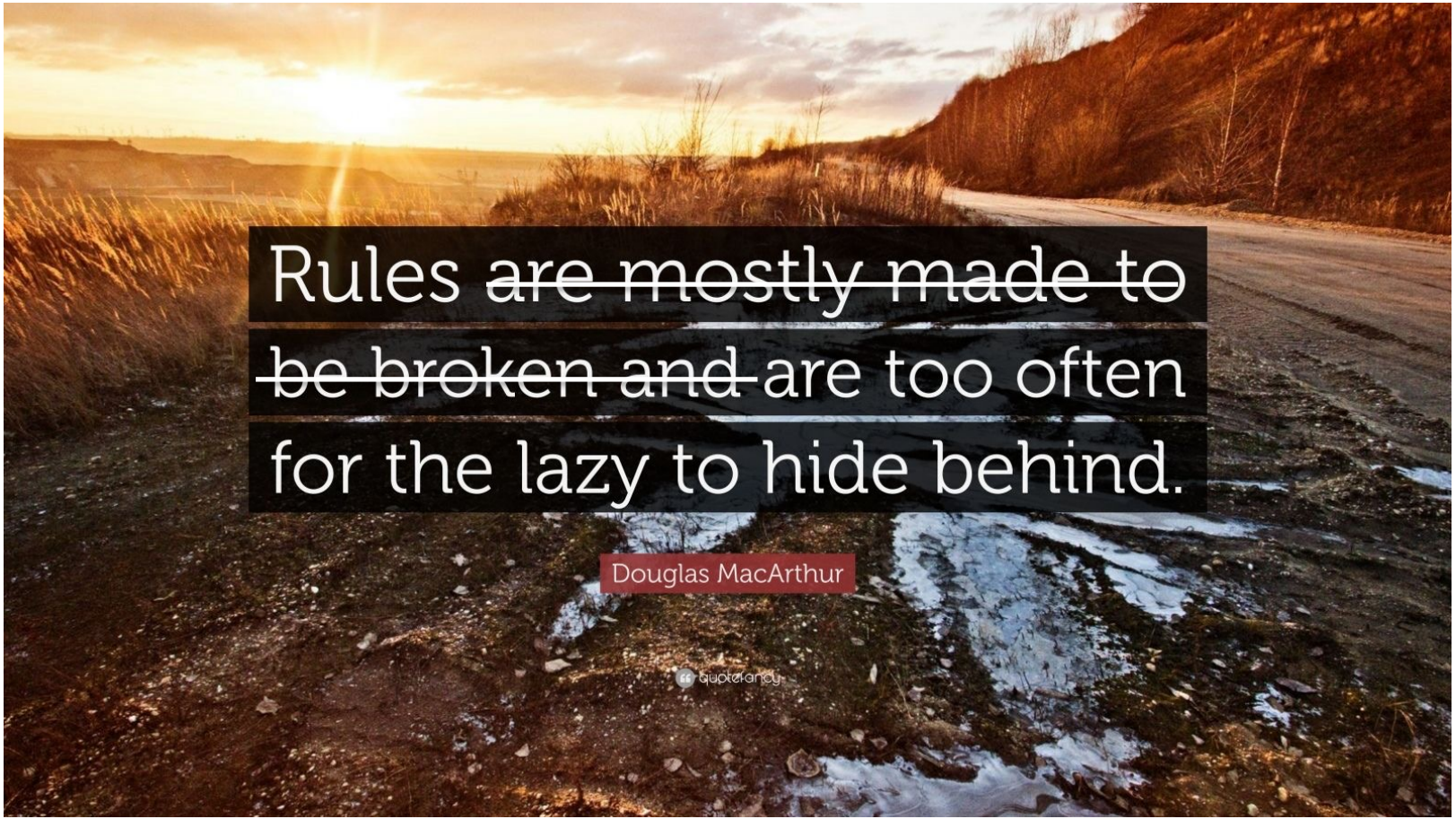
Spring Focus Workshop
IVDR – Our next challenge

Is IVDR impacting drug development beyond the intention of the regulations?

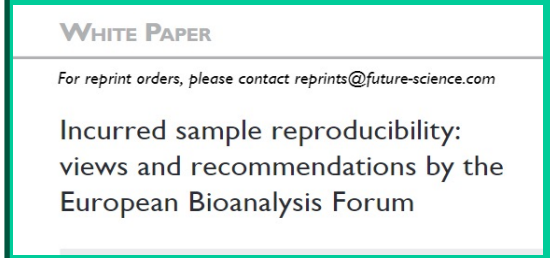
Matt Barfield, on behalf of the EBF

06-07 June 2024 – Malaga, Spain


Rules ~~are mostly made to be broken and~~ are too often for the lazy to hide behind.
Douglas MacArthur
quotefancy

3 (there are many more) current examples where in Bioanalysis we do too much – we are lazy!

Incurred Sample Reanalysis


WHITE PAPER

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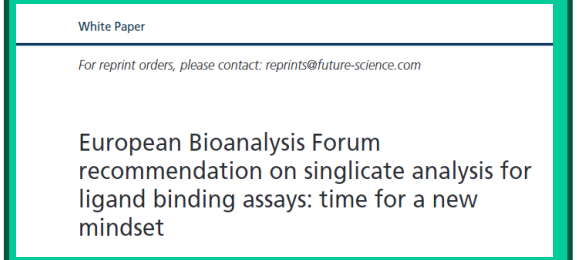
Incurred sample reproducibility: views and recommendations by the European Bioanalysis Forum

Singlicate Analysis


White Paper

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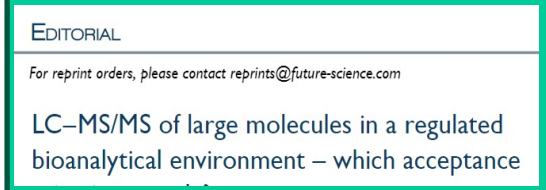
European Bioanalysis Forum recommendation on singlicate analysis for ligand binding assays: time for a new mindset

Acceptance criteria


EDITORIAL

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LC–MS/MS of large molecules in a regulated bioanalytical environment – which acceptance

Historically & today we play it safe (especially big pharma)
We don't see that trend changing

The introduction of the ICHM10

- Is this the most important document to Bioanalysts?
- Does this solve and answer all our questions around analysing PK samples?
- Does this in cases add complexity?
- Does it ensure safer drugs to patients?
- Do we over interpret and ignore what's on the most important section?

1.3. Scope

The bioanalysis of biomarkers and bioanalytical methods used for the assessment of immunogenicity are not within the scope of this guideline.

ICH Member

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 July 2022
EMA/CHMP/ICH/172948/2019
Committee for Medicinal Products for Human Use

ICH guideline M10 on bioanalytical method validation and study sample analysis
Step5

Transmission to CHMP	28 February 2019
Adoption by CHMP	28 February 2019
Release for public consultation	14 March 2019
End of consultation (deadline for comments)	1 September 2019
Final adoption by CHMP	21 July 2022
Date of coming into effect	21 January 2023

IVDR – are we already over interpreting? and who are the culprits?

&

- Our community
- Our regulatory groups
- Regulators
- ……

IVDR – An overview from a regulatory groups perspective

Out of SCOPE:

- **PK dose escalation with multiple patients per cohort** - Not in scope per U18
- **PK dose escalation with single patient cohorts** - Not in scope if it is a new patient in the next cohort

In SCOPE:

- **PK result (no adverse event or collected during adverse event)** to be used for subject management (discontinuation of treatment in case of (partial) loss of exposure, usually in conjunction with ADA data) - In scope of IVDR

IVDR – An overview from a regulatory groups perspective

cont.

In SCOPE:

- **ADA result to be used for subject screening** (as inclusion/exclusion for a clinical trial) - In scope of IVDR
- **ADA result to be used for subject management** (discontinuation of treatment in case of immune responses, usually in conjunction with PK data and potentially correlated clinical adverse events) - In scope of IVDR

- **Stability Study with Fresh sample collections -** In scope of IVDR Article 58, as samples are collected specifically for the performance evaluation and not as part of a drug trial (leftover samples would not be in scope)

The most important section in any regulation

Article 1

Subject matter and scope

1. This Regulation lays down rules concerning the placing on the market, making available on the market or putting into service of *in vitro* diagnostic medical devices for human use and accessories for such devices in the Union. This Regulation also applies to performance studies concerning such *in vitro* diagnostic medical devices and accessories conducted in the Union.

2. For the purposes of this Regulation, *in vitro* diagnostic medical devices and accessories for *in vitro* diagnostic medical devices shall hereinafter be referred to as 'devices'.

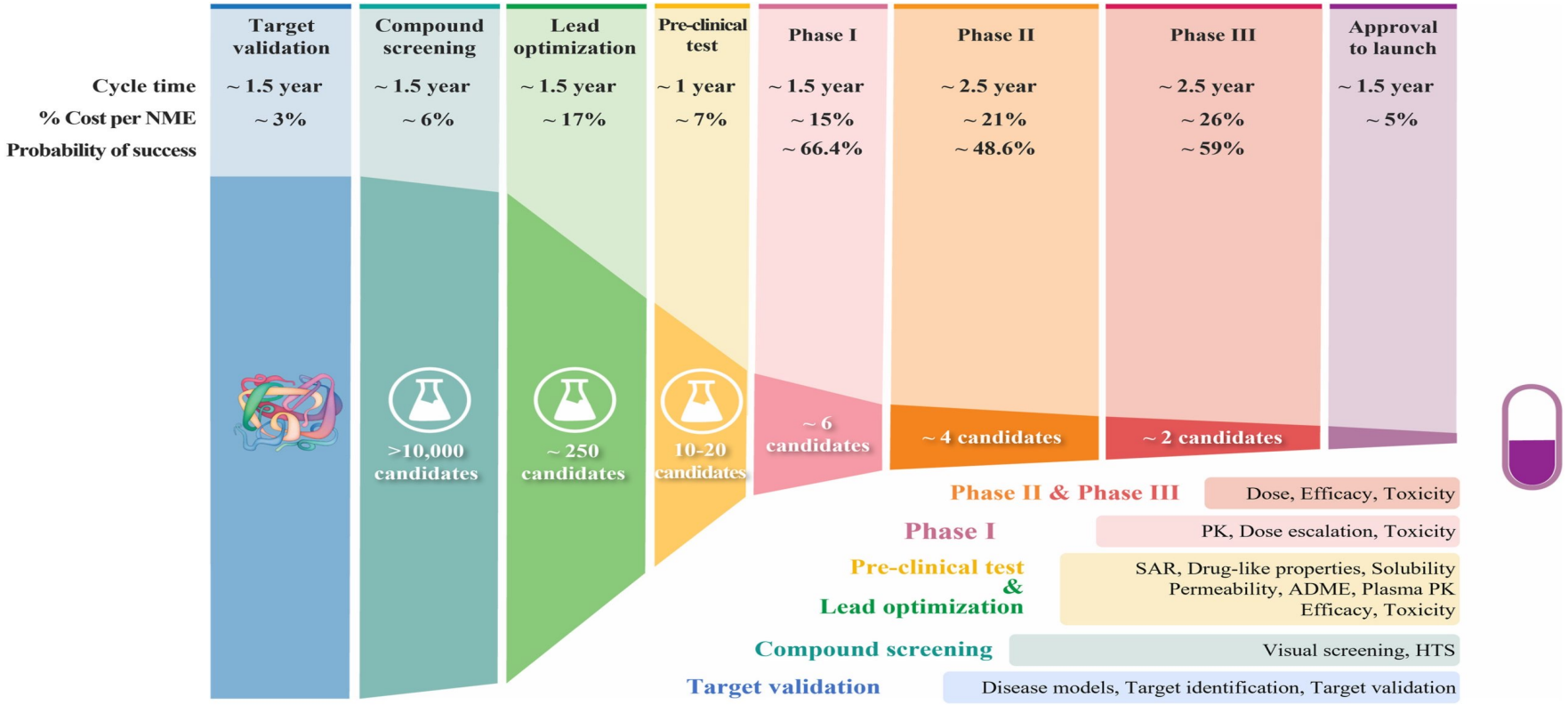
3. This Regulation does not apply to:

(a) products for general laboratory use or research-use only products, unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for *in vitro* diagnostic examination;

We have options

- We can agree and work out how to fit certain PK & ADA assays into the IVDR process
- We can push back and explain why?
  - e.g. For PK is the ICHM10 not enough to ensure patient safety?
- We can implement when we know we have a drug

90% of clinical drug development fails



What are the implications if we over interpret?

- We add complexity
- We potentially slow down the delivery of important medicines to patients
- We distract ourselves and dilute our efforts on what is really important
- We build a culture of doing more and more and more – where does it stop?
- Financial impact – doing more and slowing delivery

In the end if we over interpret who loses the most?

- Does always doing more add value to the patient?
- Does having a CE labelled PK assay make a safer drug?
- Ultimately - “what we sugest should and will not put patient safety at risk..

Acknowledgements

You all for your input into this workshop and for challenging over interpretation

Contact Information

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European Bioanalysis Forum vzw

www.e-b-f.eu