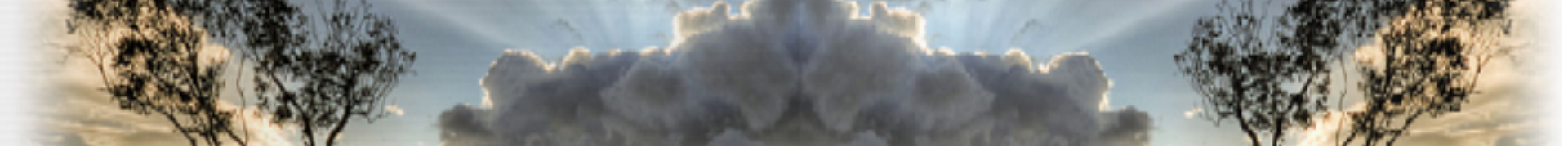


Launch Pad session 2 – Imagine: Value of doing things differently

Magnus Knutsson, on behalf of the EBF

12th EBF Open Symposium
Imagine! A New Bioanalytical Earthrise

http://www.e-b-f..eu

Agenda

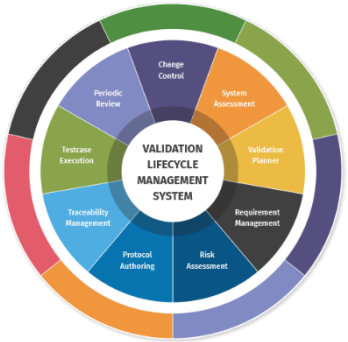
16:40 – 18:00 Launch Pad session 2

- 16:40-16:50: Intro to session – Magnus Knutsson, on behalf of EBF
- 16:50-17:10: Keynote presentation – Anja Gilis, Janssen R&D
- 17:10-17:30: Round table discussion
- 17:30-17:50: Feedback from round table discussion
- 17:50-18:00: Conclusion and next step

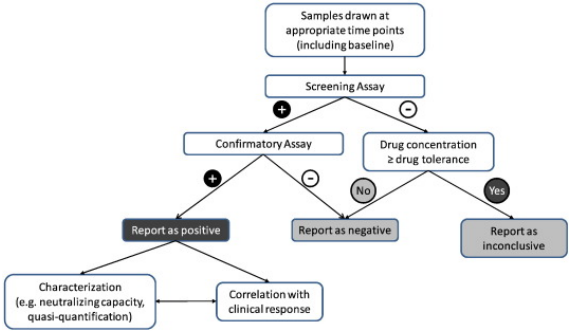
Introduction

- In this session we will discuss the risk/value of doing things differently, with focus on Risk-based approaches applicable to Bioanalysis.
- Utilization of Risk-based approaches in Bioanalysis is not new.
- In fact it is already well-integrated in some of our tasks/processes.

Computer System Validations



Immunogenicity Testing



Inspiration

- Outside CSV and immunogenicity testing it does not seem to be a widespread usage of Risk-based approaches in Bioanalysis.

- To inspire us:

Keynote presentation from Anja Gilis, Janssen R&D

Starting point for roundtable discussions

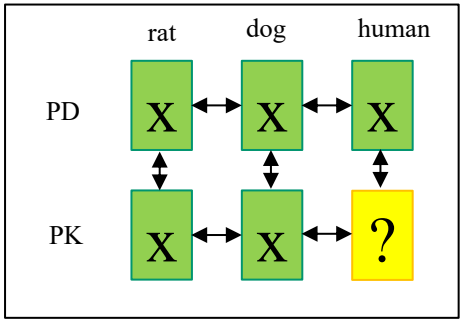
- Do we see other areas within Bioanalysis where there could be value of doing things differently based on the risk(s) associated?

Draft ICH M10 – scope section

This guideline describes the method validation that is expected for bioanalytical assays that are submitted to support regulatory submissions. The guideline is applicable to the validation of bioanalytical methods used to measure concentrations of chemical and biological drug(s) and their metabolite(s) in biological samples (e.g., blood, plasma, serum, other body fluids or tissues) obtained in pivotal nonclinical TK/PK studies that are used to make regulatory decisions and all phases of clinical trials in regulatory submissions. Full method validation is expected for the primary matrix(ces) intended to support regulatory submissions. Additional matrices should be partially validated as necessary. The analytes that should be measured in nonclinical and clinical studies and the types of studies necessary to support a regulatory submission are described in other ICH and regional regulatory documents.

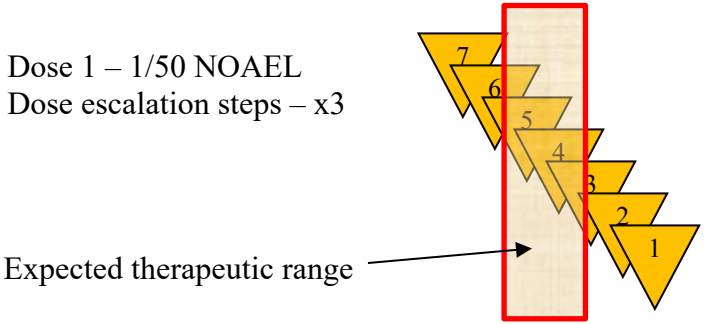
Inspirational scenario

PK-PD relationship



FIH design

Dose 1 – 1/50 NOAEL
Dose escalation steps – x3



One possibility for risk based approach application in Bioanalysis?

Round table discussion questions

- Why would you apply risk based approach in the draft ICH M10?
- Why would you not apply risk based approach in the draft ICH M10?
- Where would you apply risk based approach in the draft ICH M10?
- Do you see other areas within Bioanalysis where there could be value of doing things differently based on the risk(s) associated?
- What are needed for you to start/further use risk based approaches within Bioanalysis?