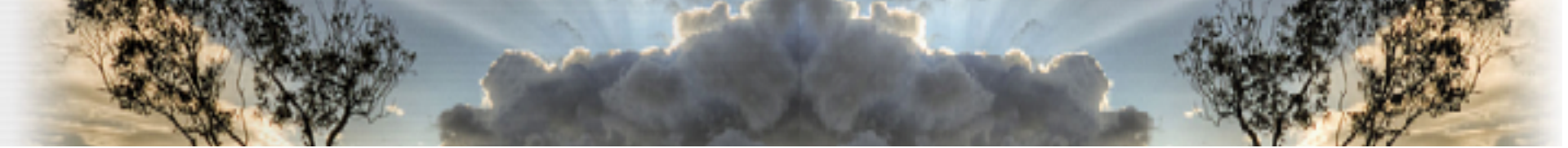

EBF Open Symposium
N° 13 From Cyberspace - Staying Connected
17-20 November 2020

ICH M10 - Introduction

Philip Timmerman/Jo Goodman
on behalf of the EBF

Disclaimer

This presentation was prepared on behalf of EBF.

The opinions expressed in this presentation do not necessarily reflect the view of any individual expert or EBF member company nor that of the ICH M10 Expert Working Group (EWG).

ICH SOP of Working Groups

Section 1.5.5 Confidentiality

- *"An expert should not publicly disclose orally or in writing the details of the ongoing discussions nor should they disclose the position of the individual parties without prior approval from the WG Members and informing the ICH MC.*

We cannot discuss the content until Step 2/3

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ICH
harmonisation for better health

http://www.ich.org/home.html

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

Rules of Procedure of the Assembly

Approval by the Assembly in its meeting on May 31, 2017

http://www.ich.org/fileadmin/Public_Web_Site/ABOUT_ICH/Articles_Procedures/ICH_Assembly_RoPs_31May2017.pdf

Quality Guidelines

Harmonisation achievements in the Quality area include pivotal milestones such as the conduct of stability studies, defining relevant thresholds for impurities testing and a more flexible approach to pharmaceutical quality based on Good Manufacturing Practice (GMP) risk management.

Safety Guidelines

ICH has produced a comprehensive set of safety Guidelines to uncover potential risks like carcinogenicity, genotoxicity and reprotoxicity. A recent breakthrough has been a non-clinical testing strategy for assessing the QT interval prolongation liability: the single most important cause of drug withdrawals in recent years.

Efficacy Guidelines

The work carried out by ICH under the Efficacy heading is concerned with the design, conduct, safety and reporting of clinical trials. It also covers novel types of medicines derived from biotechnological processes and the use of pharmacogenetics/genomics techniques to produce better targeted medicines.

Multidisciplinary Guidelines

Those are the cross-cutting topics which do not fit uniquely into one of the Quality, Safety and Efficacy categories. It includes the ICH medical terminology (MedDRA), the Common Technical Document (CTD) and the development of Electronic Standards for the Transfer of Regulatory Information (ESTRI).

Multidisciplinary Guidelines

ICH Guidelines / Work Products /

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Zip file with all Multidisciplinary Guidelines in Word format

- M1 MedDRA Terminology
- M2 Electronic Standards
- M3 Nonclinical Safety Studies
- M4 Common Technical Document
- M5 Data Elements and Standards for Drug Dictionaries
- M6 Gene Therapy
- M7 Genotoxic Impurities
- M8 Electronic Common Technical Document (eCTD)
- M9 Biopharmaceutics Classification System-based Biowaivers
- M10 Bioanalytical Method Validation

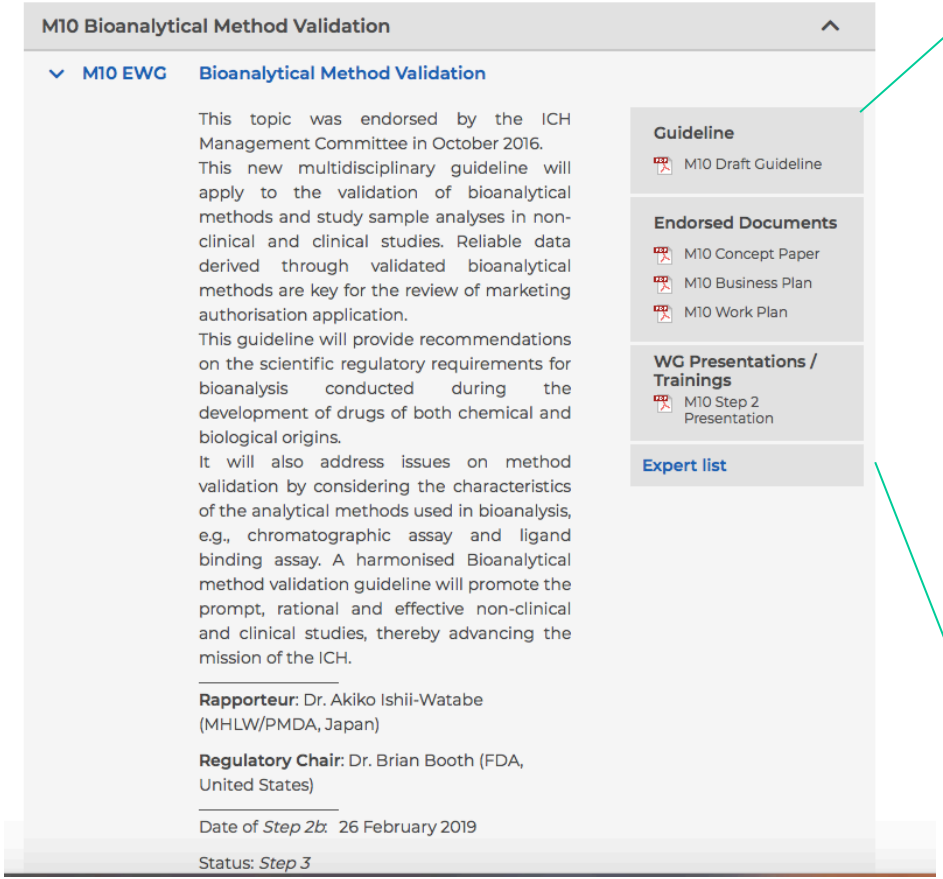
Code	Document Title	Previously coded
M10	**Bioanalytical Method Validation**	

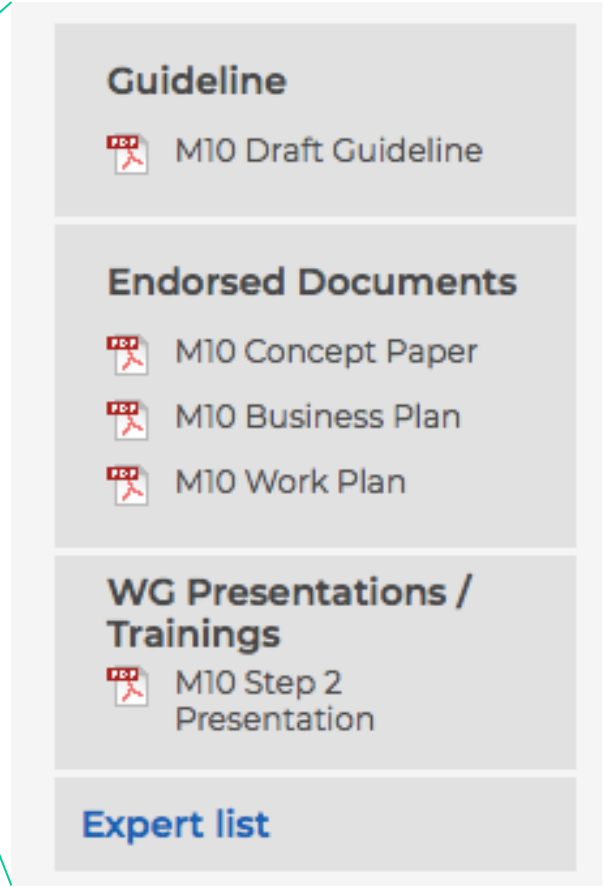
Description : This topic was endorsed by the ICH Management Committee in October 2016.
This new multidisciplinary guideline will apply to the validation of bioanalytical methods and study sample analyses in non-clinical and clinical studies. Reliable data derived through validated bioanalytical methods are key for the review of marketing authorisation application. This guideline will provide recommendations on the scientific regulatory requirements for bioanalysis conducted during the development of drugs of both chemical and biological origins. It will also address issues on method validation by considering the characteristics of the analytical methods used in bioanalysis, e.g., chromatographic assay and ligand binding assay. A harmonised Bioanalytical method validation guideline will promote the prompt, rational and effective non-clinical and clinical studies, thereby advancing the mission of the ICH.

- Concept Paper
- Business Plan
- Work Plan

Status : Step 1

https://www.ich.org/page/multidisciplinary-guidelines

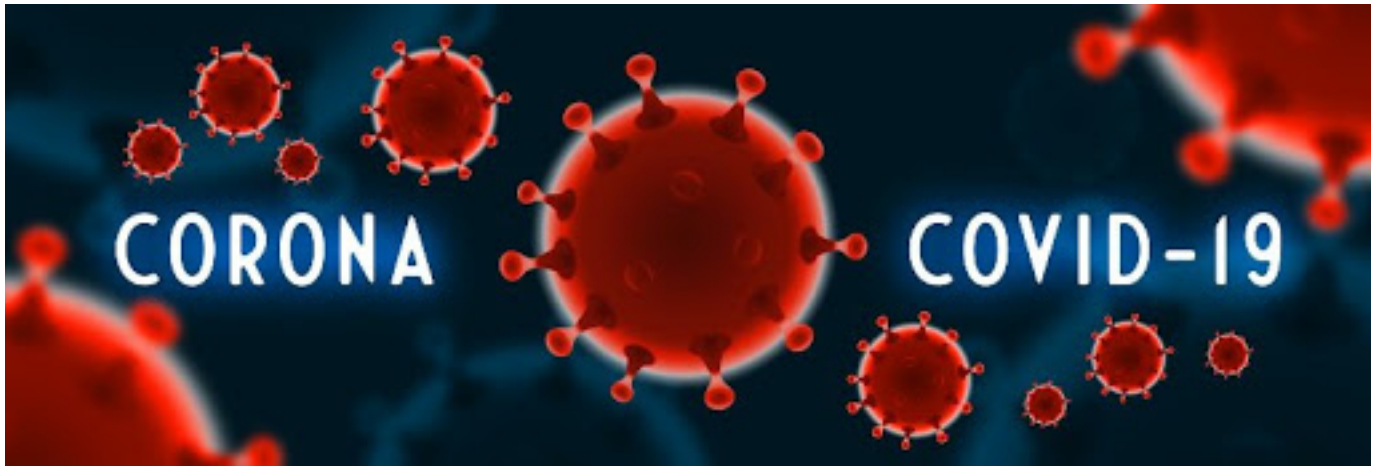




1.b. Future anticipated key milestones

Expected future completion date	Milestone
May. 2020	*Face-to-Face meeting (Vancouver) -> cancelled*
Nov. 2020	*Face-to-Face meeting (Athens)* *Updating the draft guideline by reflecting the public consultation comments* *Preparation of the draft training materials*
Jun. 2021	*Face-to-Face meeting (*Incheon*)* *Finalising the guideline* *Step 3 sign-off and Step 4 adoption* *Preparation of the draft training materials*
Nov. 2021	*Finalising the training materials*

1


CORONA
COVID-19

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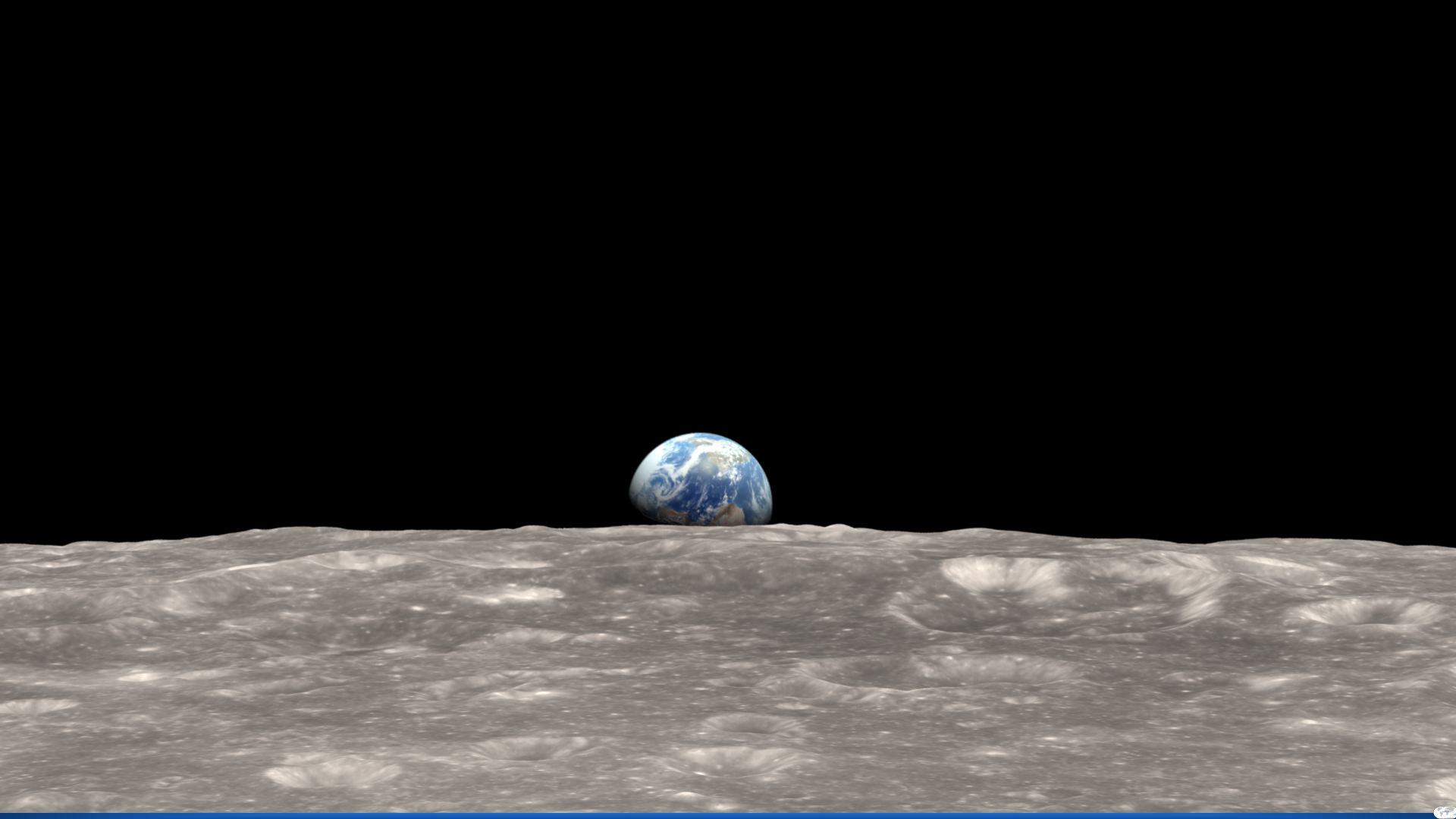
1

Currently the EWG is in “TC modus”



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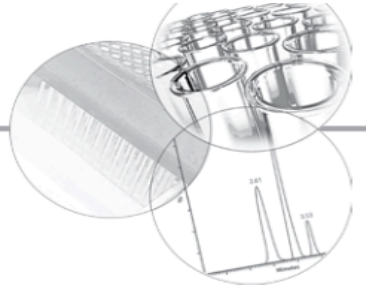
Open Letter



Request for Global Harmonization of the Guidance for Bioanalytical Method Validation and Sample Analysis

Open letter to the bioanalytical community. Sent to the US FDA/European Medicines Agency in February 2010

- ….differences in expectations or interpretation of the guidelines from individual auditors/inspectors or regional health authorities are a growing concern for the bioanalytical community…
- ….a stimulus for these countries/regions to draft or issue their own guidance documents….Although the 2001 FDA BMV guidance is often the basis of the emerging guidelines, there is an inherent risk that new sets of quality standards or nuances to the existing guidance will become effective

Desire to formally involve ICH was expressed exactly 8 y and 6 days ago on this stage

Desire to formally involve ICH was expressed exactly 8 y and 6 days ago on the Barcelona stage

Not immediately applauded as thought to be impossible

What could timelines look like for impossible projects?

An example from another industry

*May 1961: I believe this nation should commit itself to achieving the goal, **before the decade** is out, of landing a man on the **moon** and returning him safely to Earth*

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So, we have 48 days left

1961 → 1969

2012 → 08 Jan. 2021

Some observations

- A draft guideline is a draft guideline and not a final product. Changes can and will still occur from draft to final. However,
  - We see industry presenting “validated in compliance to ICH M10”
  - Wee see meeting programming “ICH M10 trainings”

- This is not without risk:
  - It disregards or dilutes industry comments during public consultation and can/will directly or indirectly lead to raising the bar
  - It obscures current guidelines (which are in effect), creating a risk of non-compliance in your current work