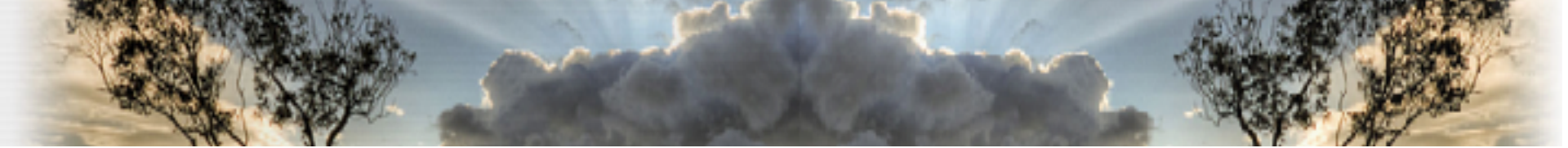


From Apollo 8 to Bioanalysis today

Philip Timmerman, EBF

12th EBF Open Symposium
Imagine! A new bioanalytical Earthrise

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

EBF

Going back in time…the bigger perspective

Last year, we highlighted 5 major challenges for Bioanalyses.

Biomarkers

Outsourcing

Regulations

Accepting exceptions

Technology

Taking a few steps back…The bigger perspective

Last year, we highlighted 5 major challenges for Bioanalyses.

Biomarkers

Outsourcing

Regulations

Accepting exceptions

Technology

In 2020, there was a lot of focus on:

Last year, we highlighted 5 major challenges for Bioanalyses.

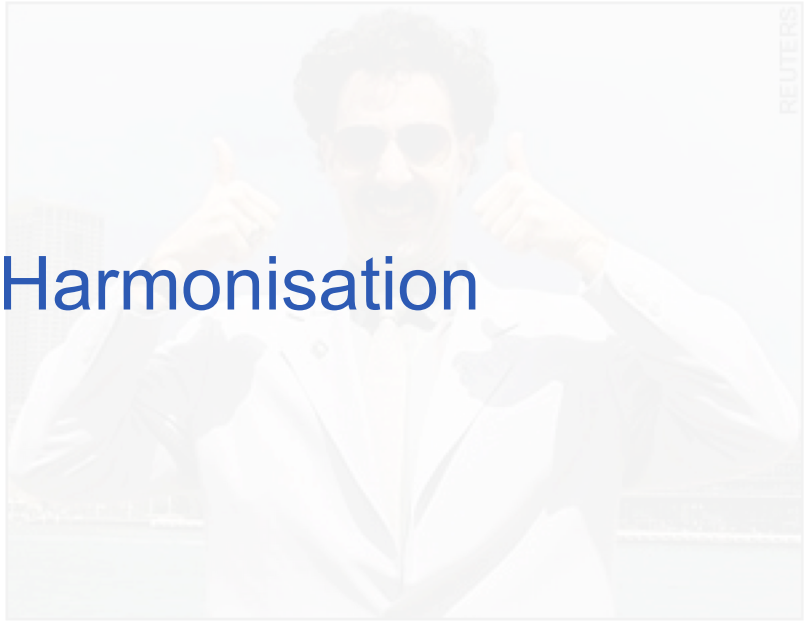
Biomarkers

Outsourcing

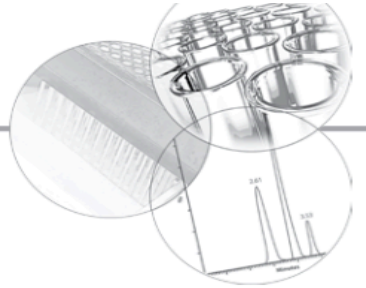
Regulations → Harmonisation

Accepting exceptions

Technology



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 7 y and 6 days ago on this stage

EBF

Desire to formally involve ICH was expressed exactly 7 y and 6 days ago on this 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*

EBF

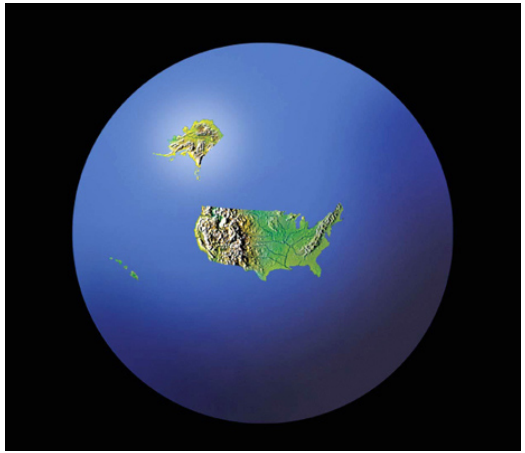
So, we have 1y and 48 days left

1961 → 1969

2012 → 08 Jan. 2021

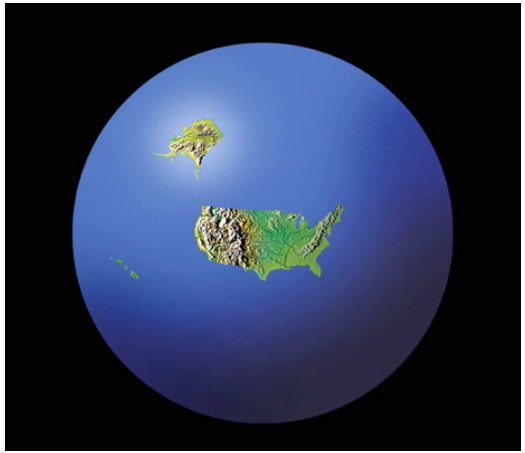
2010

- Open letter
- One BA BMV guideline applied or referred to globally
- And of course GLPs



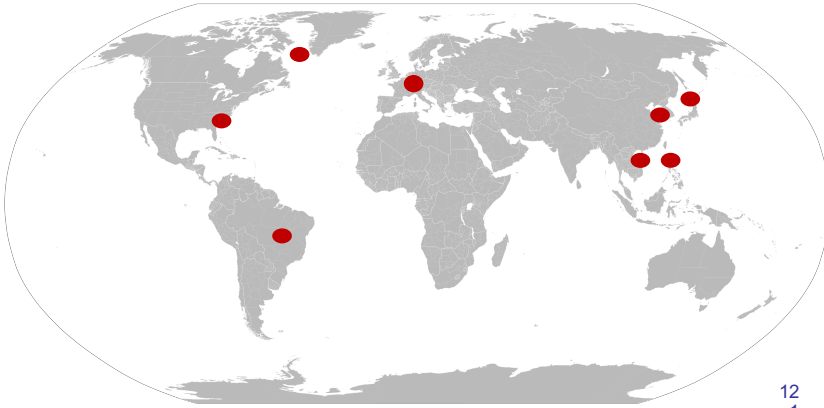
2010

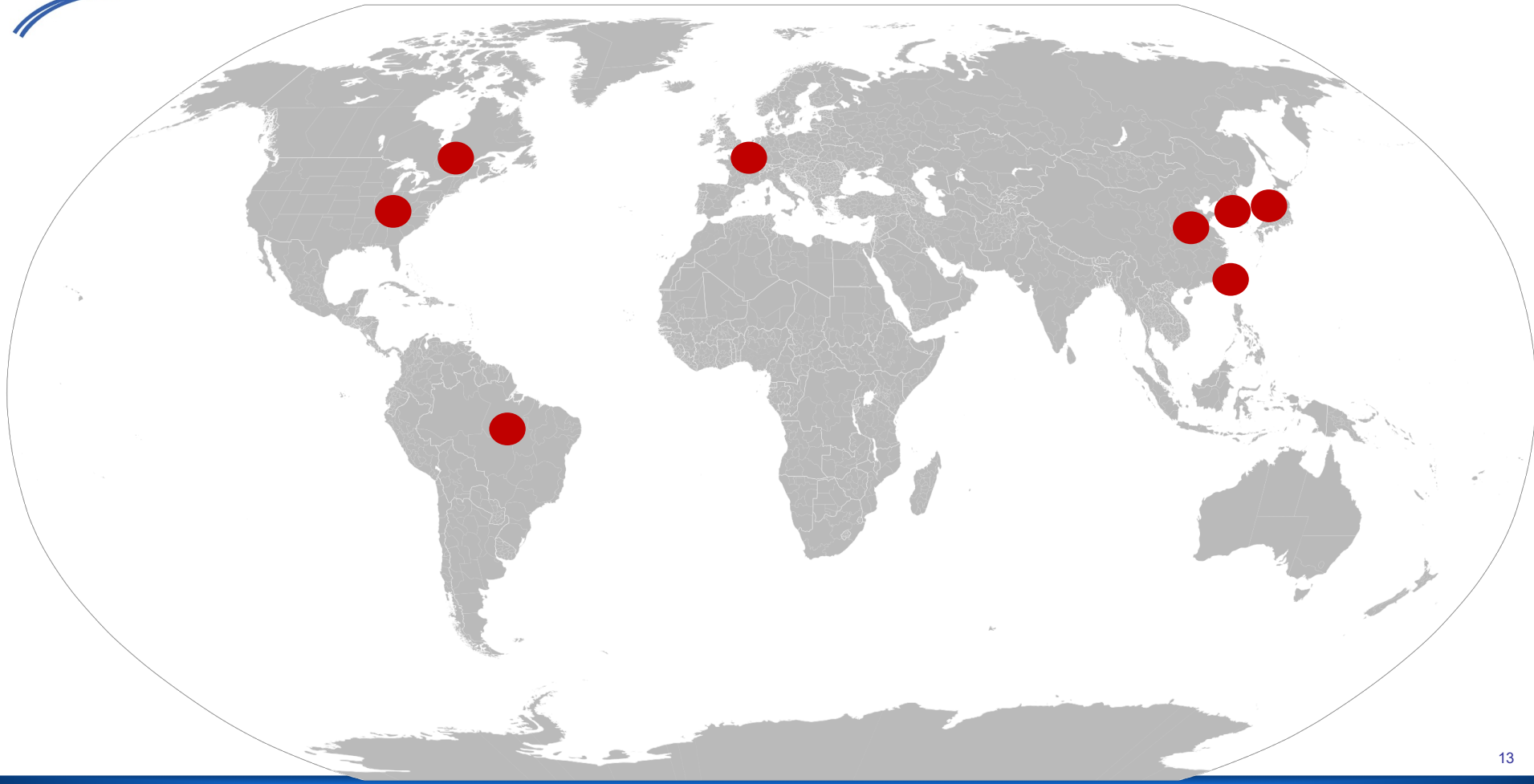
- Open letter
- One BA BMV guideline applied or referred to globally
- And of course GLPs

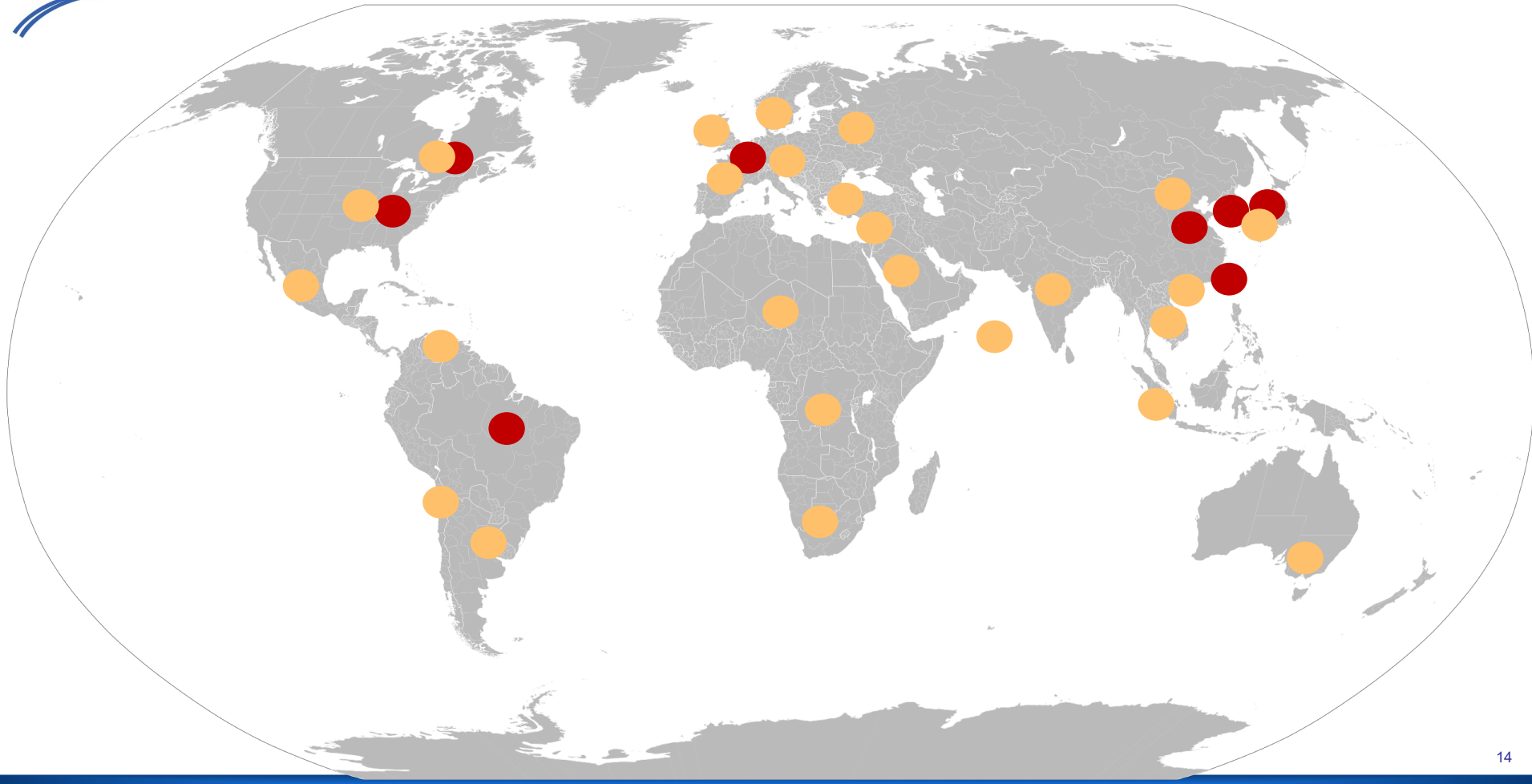


2016

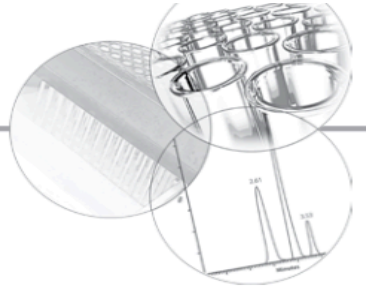
- 8 regional BA BMV guidelines
- ICH M10 approved
- And of course GLPs
- And many more additional guidelines, guidance on a variety of peripheral requirements







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

Fears from 2010 continued to be real or had become reality

- ….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


WITH SCIENCE BEING UNIVERSAL

Harmonisation

- Rocket science?

The future looks bright…ICH M10

From the 2010 Request for Harmonisation:

- *…..therefore, the undersigned would like to ask health authorities worldwide to consider a collaboration and work towards a global harmonization of the guidelines on bioanalytical method validation and sample analysis for preclinical and clinical studies...*

Yes, it's happening, and we are landing

Let’s make the landing smooth!

ICH M10 public consultation:

- EBF and EFPIA: 60+ pages of comments back to EWG
- Similar trend from other industry organisations like AAPS, JBF

….on a document which, in essence, is a harmonisation of current guidelines/guidance and based on principles which are in practice since the last 2 or 3 decades….

Did we really comment on the ICH M10?

Or did we take the opportunity to comment on disagreements with FDA, EMA, HC, ANVISA, MHLW…

Rough Terrain?

- Industry is certainly not aligned in their day to day practices/message
  - some want everything to be regulated and prescribed
  - many want more scientific freedom, especially in early development, but are hesitant (internal or external push bask) or don't know how to apply it.

- Regulators around the world are increasingly aware but at the same time unclear/differ on support for alternatives to strict BMV

- Company Due Diligence, ignorance of valid alternatives by Stakeholders (poor communication from us?) and/or increased outsourcing pushes labs into full blown BMV for studies never really intended to be in scope

We share the same pain

We seem to be unanimous on some of the major areas of ambiguity or concern

- Scope, incl. non-clinical vs. clinical
- Stability (FDC, LT…)
- Method development
- Documentation
- ISR

And need to grab the opportunities

Decision-based acceptance criteria

- Tackling also immunocapture assays or new technologies

Ethical considerations (3Rs)

From the EWG meeting in Singapore

- *EWG received a lot of comments*
- *EWG is working hard to evaluate all comments*
  - *Singapore (Saturday) Sunday → (Monday)→ Wednesday*
  - *Next F2F planned End of May 2020*
- *EWG is making very good progress on many of the important chapters of the guideline*
- *Our comments will contribute/are contributing to increase quality and interpretation and remove ambiguity in many areas*

Apollo 13

Some things we are not looking forward to

What would a Bioanalytical earth set look like…e.g.

- The exception as the basis for the guideline
  - '483' for regulatory "non compliances" but within scientific excellence
- △ interpretation by △ inspectors of the same or △ region on a given requirement
- complex and △ guidelines by △ organisations on the same themes
  - Data integrity expectations in different regions, GCP/GcLP/GLP
- Requirements unique in 1 region
- (Us) Abandoning or stifling new technology because fitting them into a regulatory straight jacket (too soon or at all)
- No opportunity to interact with HA

Let's plan for Mars

- What will EBF's focus on in the near future?
  - Interactions and collaborations
  - Scientific *vs.* regulatory requirements for Biomarkers (CoU)
  - The lovely worlds of ADA
  - Manageable requirements for DI and e-environment
  - New technologies / new modalities (e.g. automation, qPCR, C&GT)
  - Common understanding of GXPs for Bioanalysis
  - Microsampling
  - Continued discussions on harmonised decision based criteria for PK assays
  - On all of above: opportunity to interact with HA in our meetings

The bioanalytical King Midas touch…

MIST

CSV

PPB

DI

Turning everything we touch into gold…

BIOMARKERS

AMS

Early Development

GxP

But first ICH M10

For the next generations of bioanalytical scientist

let’s get it right

HA

Stake holders

Industry BA community

HA

Stake holders

Industry BA community

Contact Information

Questions: info@e-b-f.eu

European Bioanalysis Forum vzw

www.e-b-f.eu