

**Philip Timmerman**  
**Janssen Research & Development**

EBF 7<sup>th</sup> Open Symposium Barcelona | 19 November 2014

Pictured above: The structure of HIV.

## **Disclaimer**

The views expressed in this presentation are my own and may not necessarily represent the views of Janssen R&D

# 1. Introduction

**Today, the future looks bright**

- fantastic array of new analytical platforms
  - **Increased** sensitivity –selectivity - chromatographic separation power – miniaturization - power of supporting IT tools - accessibility to knowledge and information - data mining potential
  - **Increased** bar.....
- And fantastic portfolios in drug development
  - To apply all of the above

**I wish I was 30 years younger...**

but, I'm not....

**Is our bright future defined by  
developments in science and  
technology alone?**

**Can we learn from the past?**

**Let's take trip down a memory lane**



# **50 years of Bioanalysis: a continuously changing landscape.**

*A complex world of Regulations  
(or A world of complex regulations?)*



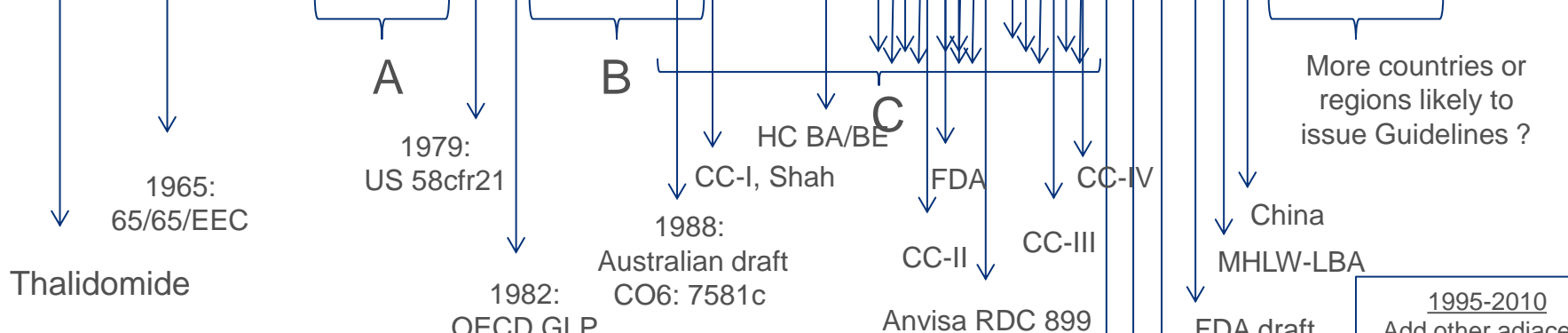
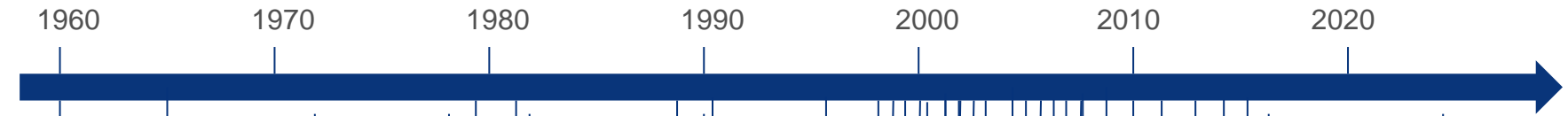
Continuous breakthroughs in  
Analytical Science



# A snapshot of this marriage

## technology

mcg/mL	Sub mcg/mL	ng/mL	Sub ng/mL	pg/mL	Sub pg/mL?
TLC Immunoassays bioassays	TLC, GC (LC-UV) immunoassays	GC <sup>2</sup> , GC-MS GC-NPD/ECD HPLC-UV/fl immunoassays	GC <sup>2</sup> , GC-MS GC-NPD/ECD HPLC-UV/fl LC-MS/MS, Old school Immunoassays	LC-MS/MS, New generation Binding assays AMS ICP-MS	New generation LC and MS(/MS) and Binding assays

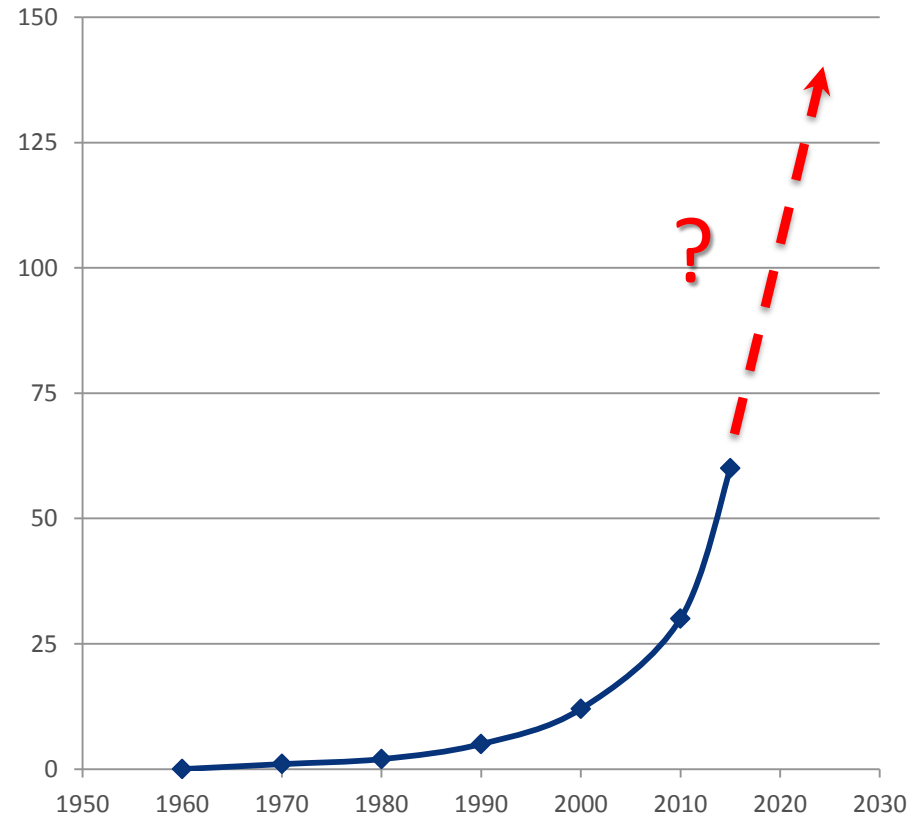


## Regulations

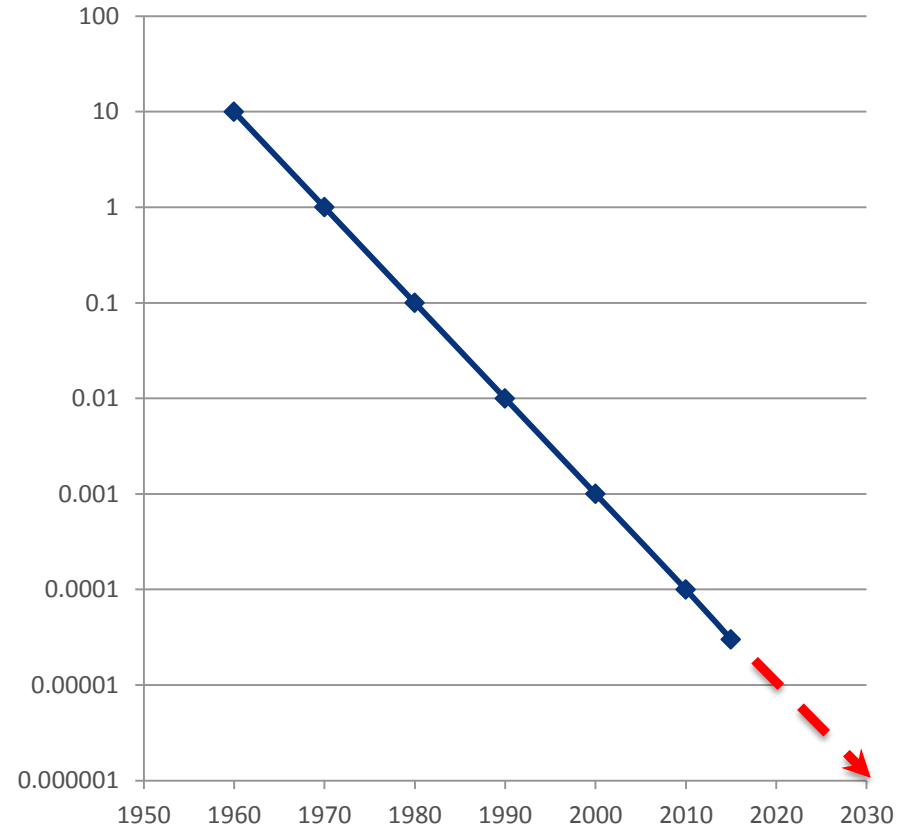
- A. scientist adopting home designed quality systems
- B. scientist shopping for inspiration in other areas – peers, DIN, EPA,..
- C. multiple countries issuing regulations of BA included in BE guidelines

# The future

## regulations



## Assay sensitivity, ng/ml



**What gets the job done ?**



## Did we find the right balance?



- Do we need more regulations and sensitivity to do a good job?
- Did we lose sight on real challenges in our industry?
  - Safer drugs
  - More effective drugs
  - including disease markers/diagnostics
  - The ever increasing economic pressure
  - From internally focused research to an external model
  - globalization

Will project management and communication of science be more critical than outstanding science?

## Some hurdles form the past



Or we often got caught in our own a web

**Technology**

**Process**

**SOPs**

**Rules**

**BusyBusyBusy**

# New technology in the past: push or pull?

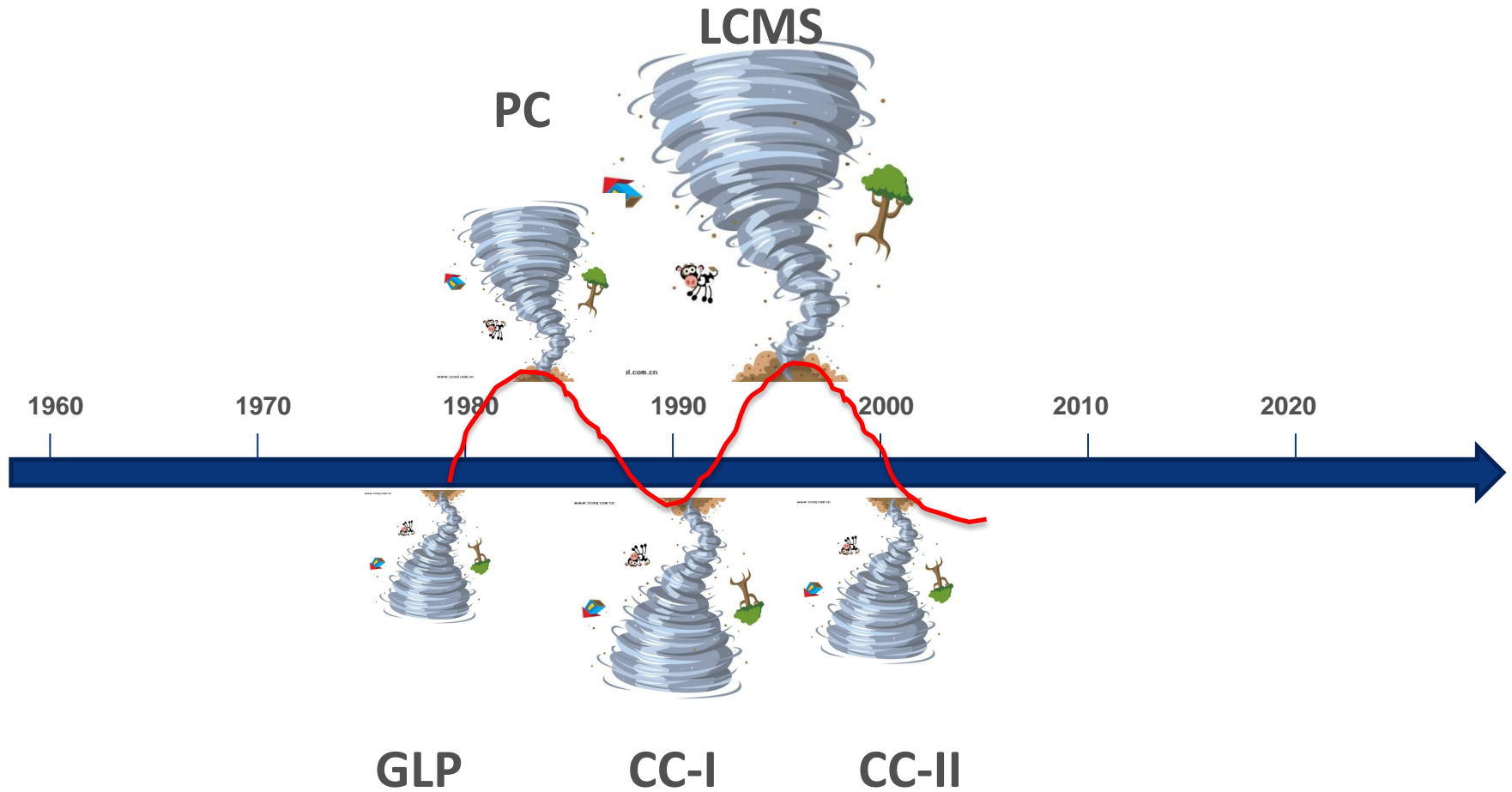
Anal. Chem., **1987**, 59 (13), pp 855A–858A

“ While neither  
LC/MS nor SFC/MS  
seems destined to *replace*  
GC/MS, they will become  
increasingly important  
tools in the analytical  
laboratory. ”

- Where is GC/MS today?
- Where is SFC today?

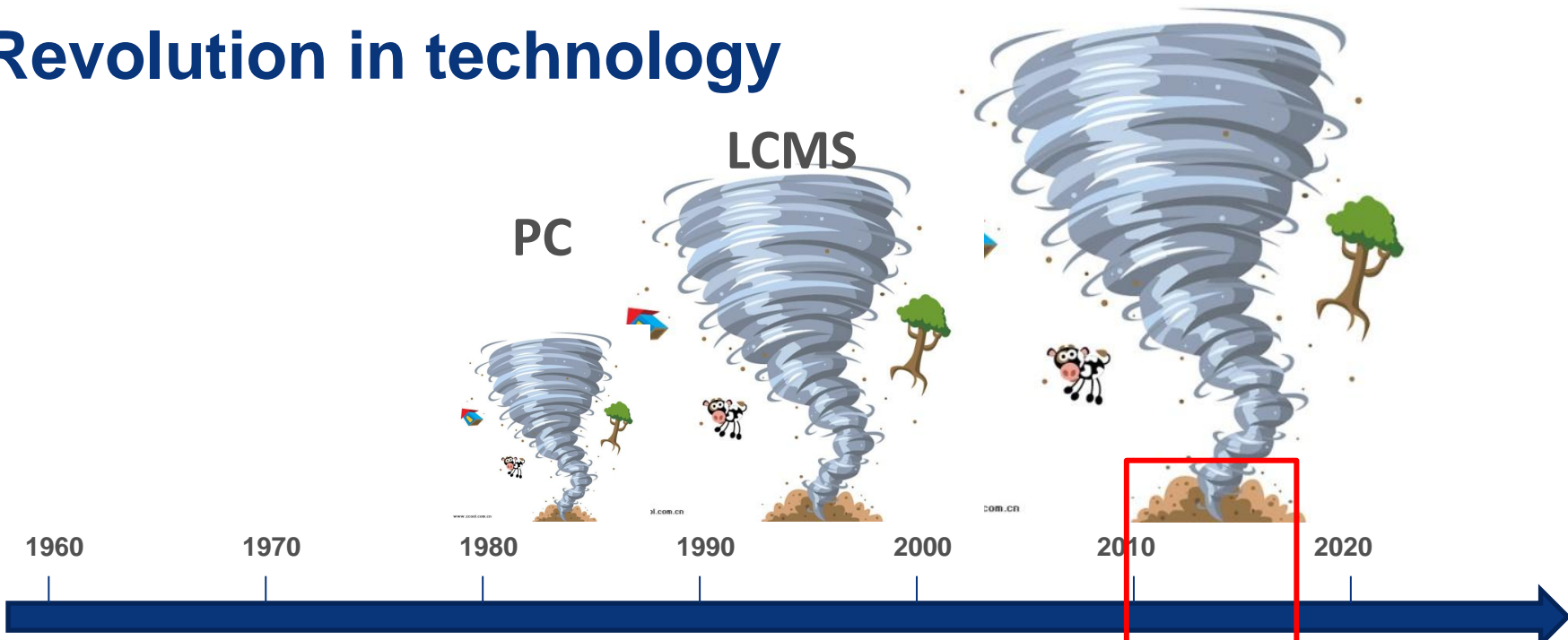


# Revolution in technology

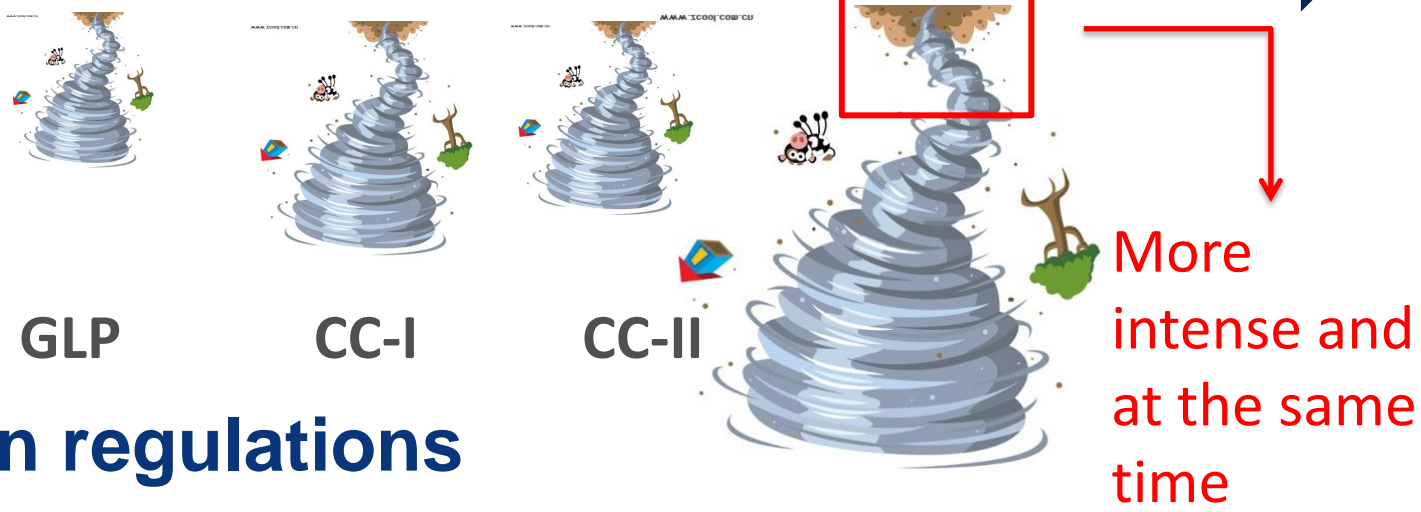


# Revolution in regulations

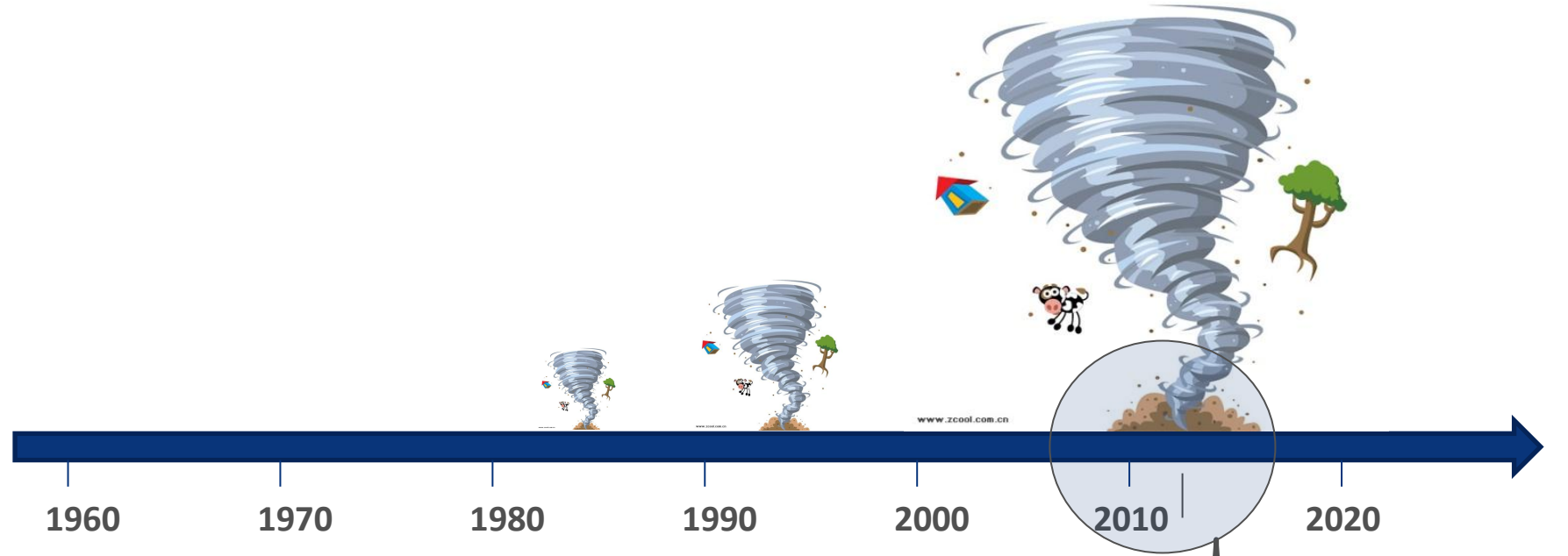
# Revolution in technology



# Revolution in regulations



More intense and at the same time



- New technology**
- New interfaces
  - Next generation MS
  - Miniaturization
  - Innovation in sample preparation
  - Peptide/protein analysis
  - The web...

- New applications**
- New scaffolds
  - portfolio changes
  - New disease targets
  - Biomarkers/Diagnostics
  - Microdosing
  - Micro sampling
  - Metabolites
  - Multi-analyte applications

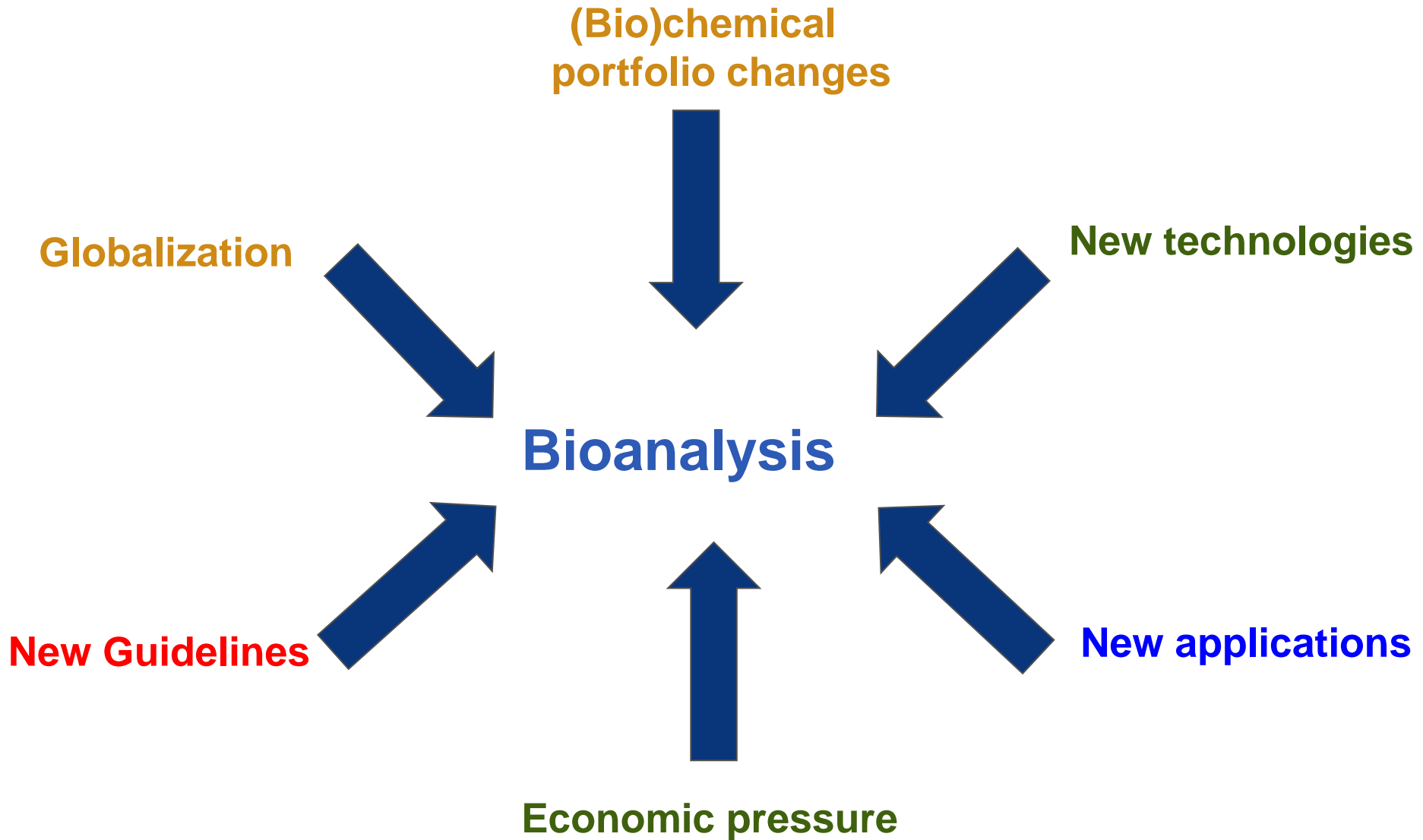
- New Guidelines**  
(or expectations from existing regulations)
- EMA, FDA, Japan, Brazil, China
  - GLP – BE – MIST
  - Immunogenicity, biosimilars

- Globalization**
- EU
  - NA
  - APAC
  - LA

- Economic pressure**
- Clear.....doesn't need explanation



# So, here we are...



# Or, here you are?

**(Bio)chemical portfolio changes**

**Globalization**

**New technologies**



**New applications**

**New Guidelines**

**Economic pressure**

# How to manage the future challenges?

- We will need more than our IQ
- We will need to
  - Connect
  - Translate - contextualize
  - See The bigger picture - Rise to the occasion
  - Communicate
  - And above all...Imagine

# Connect

# Connect outside Bioanalysis



**Bioanalysis**

**PK,  
metabolism**

**Tox/Path**

**QA**

**PD,  
Clin-pharm**

**Chem-  
Pharm**

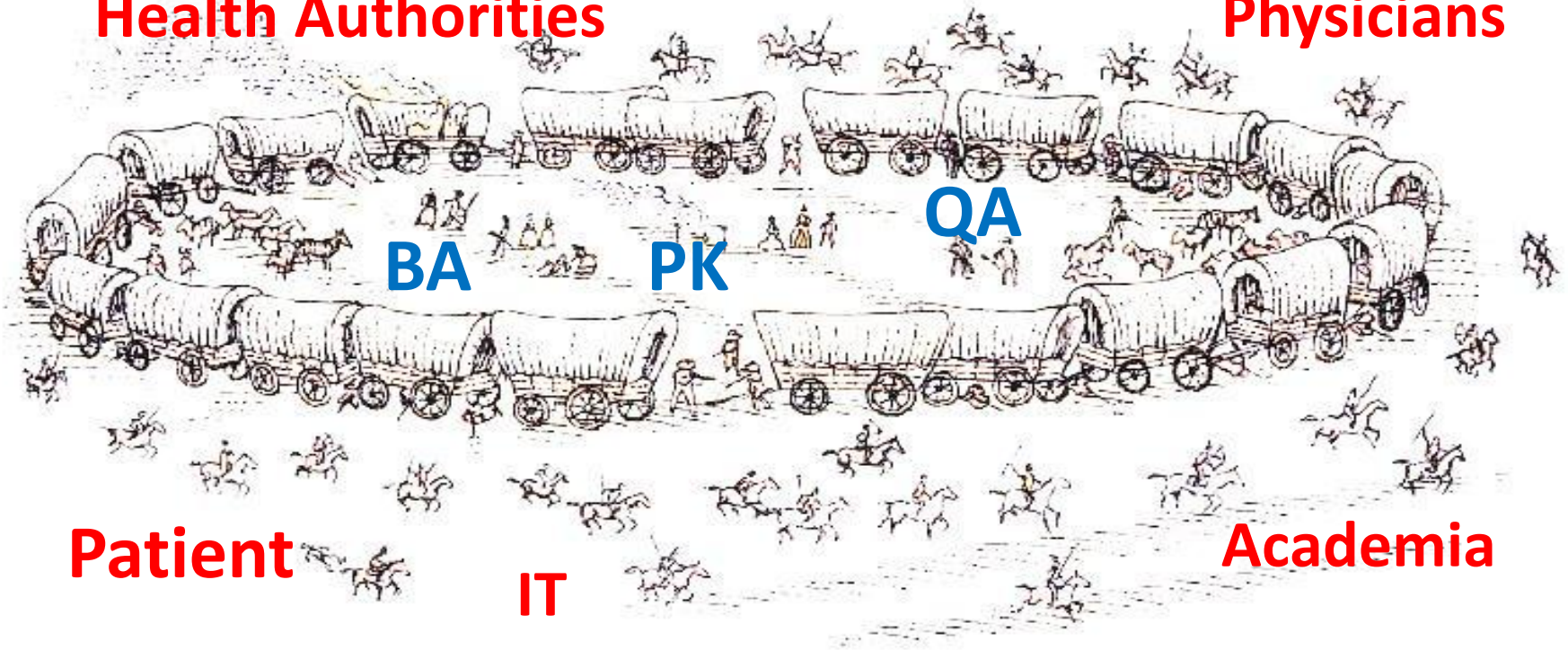
- Challenge your and others' potential silo thinking
- Create open environment to learn, interact and share
- Stimulate interdisciplinary discussions
- Try to understand the real question

Recent EBF Biomarker Recommendation is actually a good template to approach any scientific question asked in bioanalysis. [Bioanalysis](#). 2012 Aug, 4(15):1883-94.

# Connect outside Bioanalysis

**Health Authorities**

**Physicians**



**Patient**

**IT**

**Academia**

Be aware that, when stepping out of your silo, you may enter the next silo

Great ideas may come from outside Pharma R&D!

**Translate - contextualize**

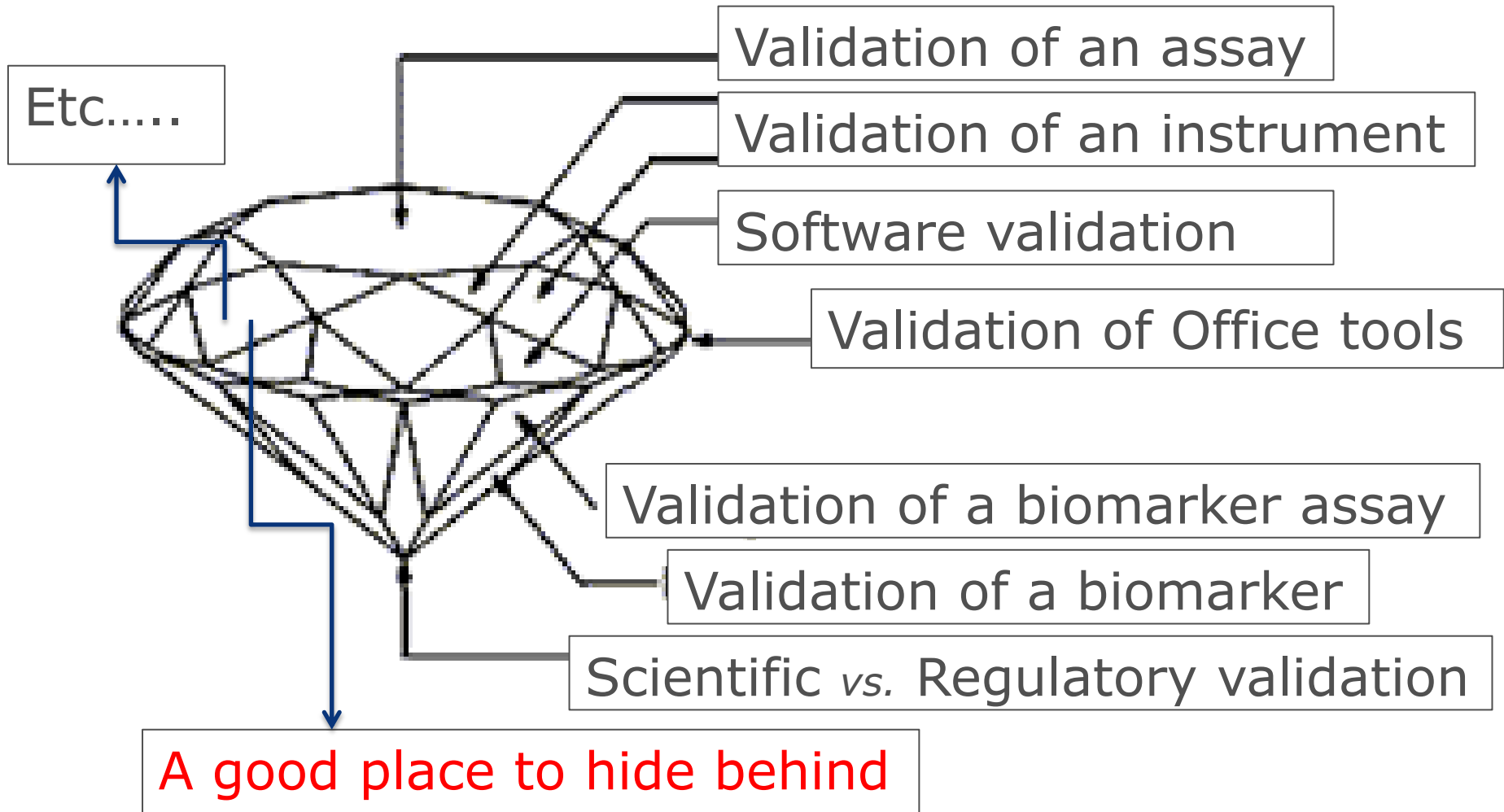


An example:  
Validation, a true diamond?



.....which can be blinding us

# Ensure awareness of different meanings of validation?

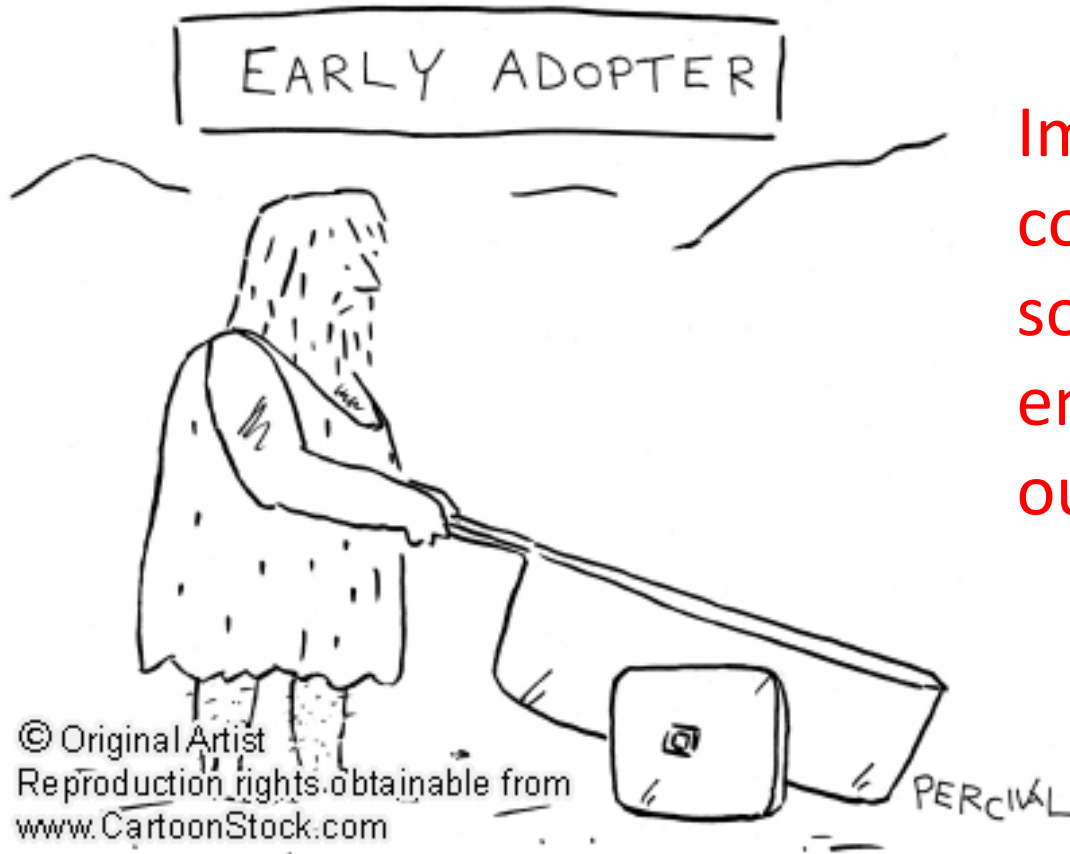


It can add value and clarity not to use the word 'Validation' in isolation, but add **context** on why and what kind of validation is needed (e.g. science, compliance)

# The bigger picture

# An example: New technologies

Early adopters are needed, but we need to be critical.....



Implementing half  
cooked technology too  
soon in a regulated  
environment can harm  
our reputation

# But let's not be too critical




*Ryan is a late adopter*

# Understand the bigger picture

## New technologies

We have a hard time positioning new technologies

- Over-validating?
  - Risk averseness?
  - Playing it safe.....or.....mixing up validation requirements from different areas
- Failure to engage (late engagement) with our stakeholders
  - Risk of the single vision?
  - Not understanding the full potential?

 Full understanding of new technology's value, its area of application and (absence of) validation requirements should prepare us for success



# Understand the bigger picture **the patient.**

- What does the patient need?
  - More efficient, safer drug and affordable drugs faster at his/her disposal.
  - Better diagnostic tools to predict or follow disease development in outpatient environment
  - Our attention
- Benefits for the patient = benefits for society

**And.... never stop using our imagination**

**"Where No Man Has Gone Before"**





Diabetes jewelry for administering insulin through the skin.

# The 'tricorder'.



Blood-testing device that sits under the skin and gives signal via a mobile phone. The wireless prototype can simultaneously check for up to five different substances in the blood

Source: <http://www.bbc.co.uk/news/health-21841829>

The new handheld device will be able to gauge the effects of smoking and junk food on the body.

Source: <http://www.nigeriadailynews.com/health/>

## Top 10: Star Trek Technology That Actually Became Real

1. Tricorders
2. Telepresence
3. Torpedo Coffins
4. Geordis Visor
5. Universal Translator
6. Phasers
7. Tractor Beams
8. Hypospray
9. Communicator
10. Transparent Aluminium

<http://www.gimmedigital.com/21943/top-10-star-trek-technology-that-actually-became-real/>



# Nestle Researchers are Looking to Create a 'Star Trek' Replicator or Food Synthesizer

*3D printing News, June 24 2014*

11



So, beyond the horizon....

A photograph of Spock from Star Trek: The Motion Picture, wearing his blue uniform and leaning forward in a bridge setting. The background shows a window with a starry space view and some control panels with glowing lights.

**It's Bioanalysis, Jim, but  
not as we know it....**



# In conclusion

The future is bright but also the challenges are real.

The next generation bioanalyst needs to:

- **Be flexible** to keep up all new developments
- **Get involved** to help develop the right tools/processes
- Actively **connect** outside own scientific area to learn and share
- **Translate**
  - scientific questions into relevant bioanalytical language
  - regulatory questions into relevant scientific language
- **Communicate** bioanalytical requirements, potential and hurdles in a language all understand
- **Challenge** and invite challenge....

## And above all

....don't be afraid to be the kid you once were (or still are). Remain **authentic** to ensure that the great diversity of ideas can keep bubbling up.

**Or to paraphrase Graham Parker**

**Be the 'kid with the butterfly net'**

**When you close your eyes  
You don't see a thing  
You just remember  
That you were meant to have wings**

<http://www.songlyrics.com/graham-parker/the-kid-with-the-butterfly-net-lyrics/#WXLtQqLVtwd3bxcR.99>

**That being said, thank you and .... beam me up!!**

