Making Harmonization a Reality

Kathy Lee
Executive Director - CMC Regulatory

Genentech, A Member of the Roche Group

Alphabet Soup of Reliance

IDMP

FHIR

ICMRA

KASA

EAEU

CTD

QbD

ORBIS

FDA

EMA

ICH

PIC/S

WHO

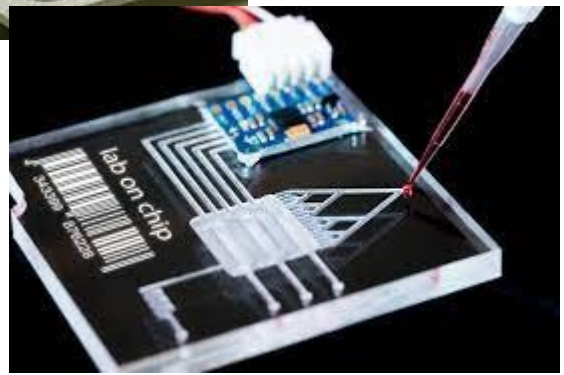
OPEN

PQ/CMC

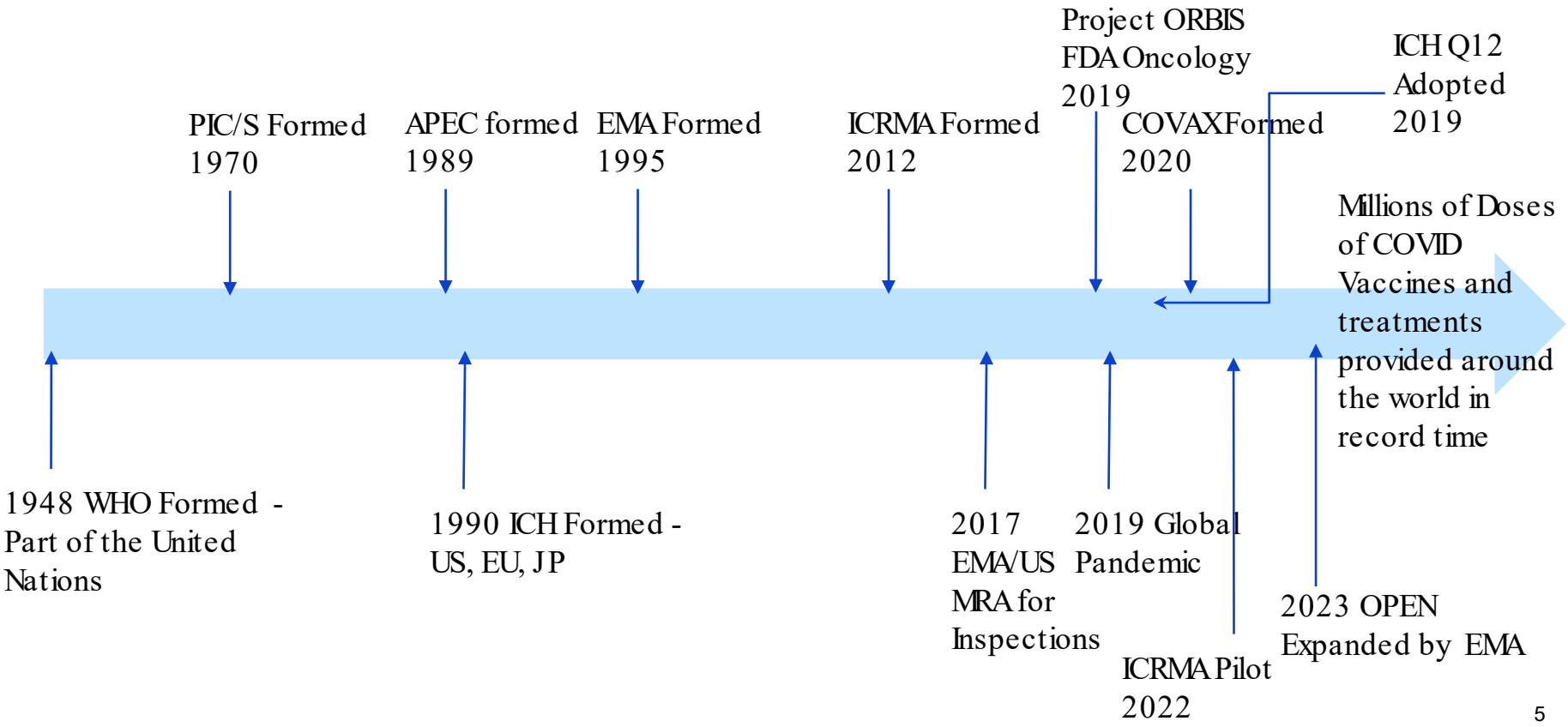
Paper to Electronic to the Cloud

“Process is the Product” to Predictive Modeling

- Process was the Product
- Patient Focused Drug Development
  - QTPP/CQAs
- Specifications
  - No longer solely reliant manufacturability
  - Platform/Prior Knowledge
  - QbD
  - PAT
- Robust Analytics
- Use of Predictive Modeling



Selected History of Harmonization (Not Quite Reliance)



"Alone we can do so little, together we can do so much."
Helen Keller

Reliance

- Collaboration
  - Across Industry and Regulators
    - WHO and ICRMA
    - Access Consortium
    - EMA OPEN Framework
    - ORBIS
- Electronic Tools
  - Cloud Based submissions
  - Structured Data
  - Goal of one submission to many Health Authorities
- Innovative Science and Regulatory Strategies
  - Risk-Based Submissions and Reviews
  - Acceptance of new science
  - Requires transparency
  - Understanding the Why and the What behind HA requests and requirements

Doing now what patients need next