Making Harmonization a Reality

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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)

1948 WHO Formed - Part of the United Nations
1970 PIC/S Formed
1989 APEC Formed
1995 EMA Formed
2012 ICRMA Formed
1990 ICH Formed - US, EU, JP
2012 ICRMA Formed
2019 COVAX Formed
2017 EMA/US MRA for Inspections
2019 Global Pandemic
2019 FDA Oncology Project ORBIS
2022 ICRMA Pilot
2023 OPEN Expanded by EMA

Millions of Doses of COVID Vaccines and treatments provided around the world in record time
ICH Q12 Adopted 2019

Roche
“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