
Digital Technology, an essential enabler to meet the burden of a pandemic, and Beyond...

Bénédicte Lebreton

Global Head, Pharma Technical Regulatory Biologics Development Genentech/Roche





Business Continuity Challenge

Communication, Collaboration, Inspection experience

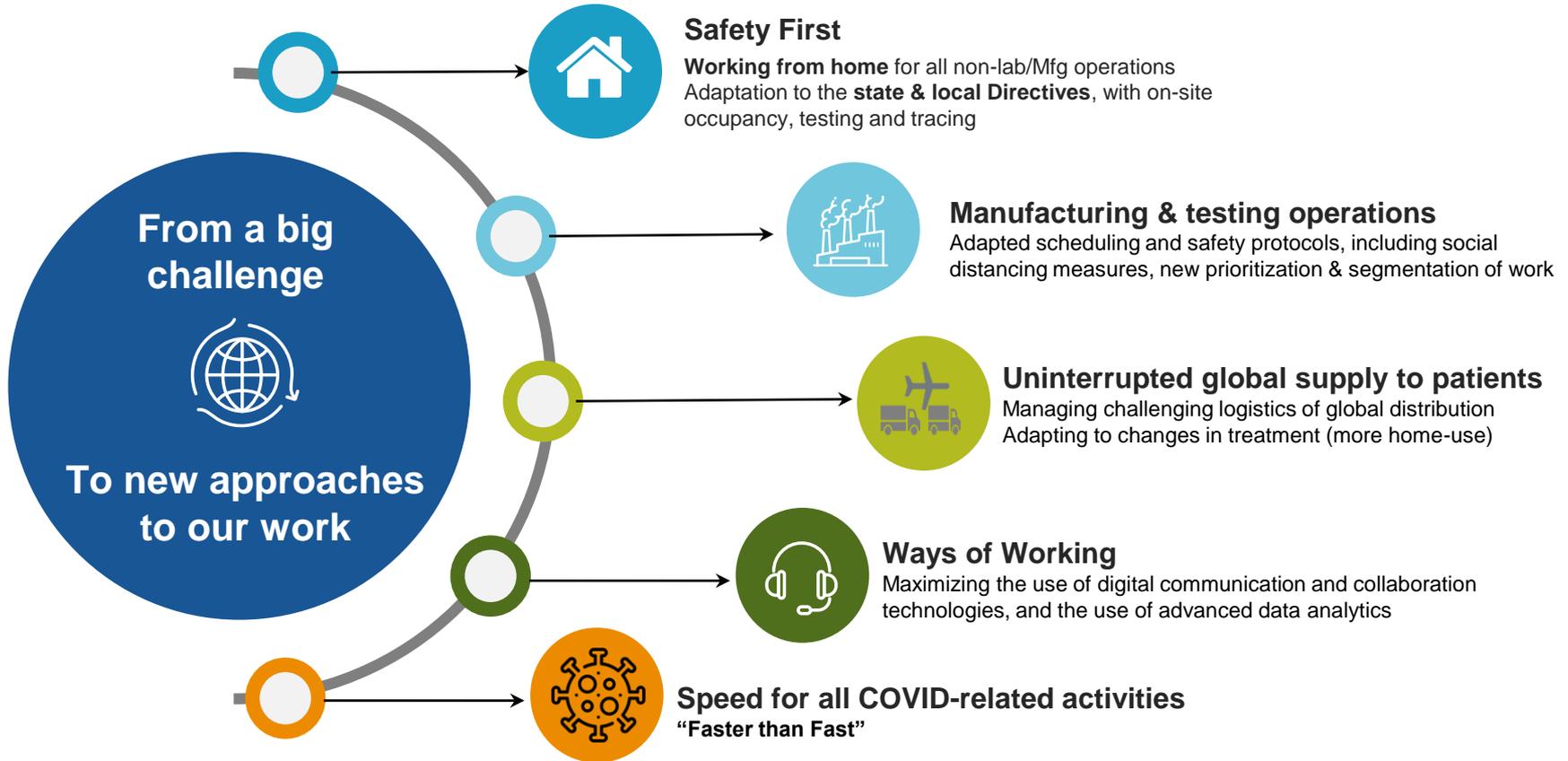
Adapting to changes in drug treatments

Digital Technologies for faster information flow and enhanced Patient Safety

Towards New Ways of Regulatory Affairs

Concluding Remarks

Business Continuity Challenge



Ways of Working - Extended Reality

Technologies for virtual presence



RealWear Head Mounted Tablet combined with Zoom conferencing to support **remote hand-free** collaboration as “**Telepresence Stack**” for:

- *Training*
- *Tech & Method Transfers*
- *Troubleshooting*
- *Remote Internal & Cross-company audits*
- *Inspections: walkthrough or on-demand tour*



Benefits

Supporting “business continuity”, personnel safety & faster access to experts.

Easy deployment



Inspections during a pandemic

Flexible, Adaptable



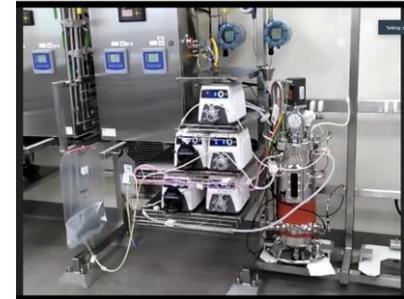
- Fully remote/virtual **or**
- Hybrid with one inspector on site and others remote



Different approach to inspection management and inspection logistics

- Global manufacturing and laboratory facilities are under different local safety directives (social distancing, scheduling, testing)
- Global travel restrictions
- Use of a wide range of communication technologies

Remote Facility Walkthroughs



Adapting to changes in drug treatments and clinical priorities

To reduce risk of COVID exposure in clinics while maintaining treatment compliance

Changes in administration (Intra-Venous to Sub-Cutaneous, combination, faster administration) **and/or use environment** (clinic vs home).

Considerations:

- Human factors: users, environment, instructions, medication errors, new dose
- Product quality: additional in-use stability data; product combinations
- Microbial control

Accelerate and expand access

- ⇒ New INDs/IMPDs
- ⇒ Acceleration of global reviews
- ⇒ Supply “Direct-to-Patient”

Leveraged HA Guidances on conducting clinical trials, supporting availability of medicines during COVID-19 Pandemic

Patient-Centric control strategy

Increasing speed and insights



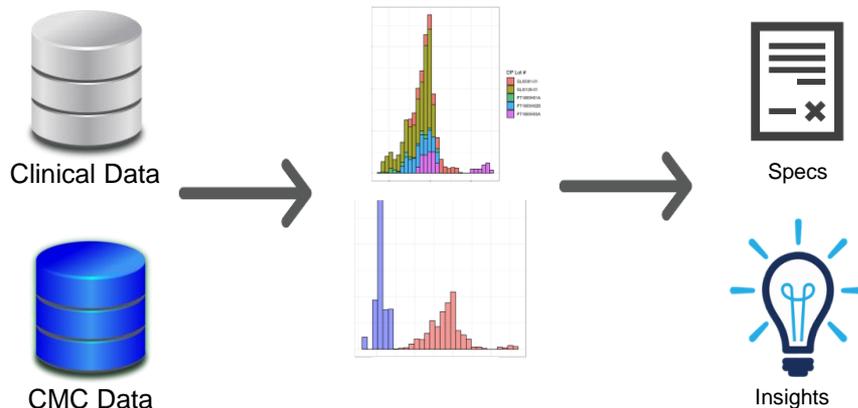
Increasing speed and gaining deeper insights in connecting clinical output to the product quality profile.

- Global digital solutions for connecting multiples systems and datasets
- Setting up new advanced data analytics



Benefits

- Shorten analysis time, authoring, internal review/compliance checks
- Set more patient-centric specifications
- Enable lifecycle management
- Increase overall understanding and insights



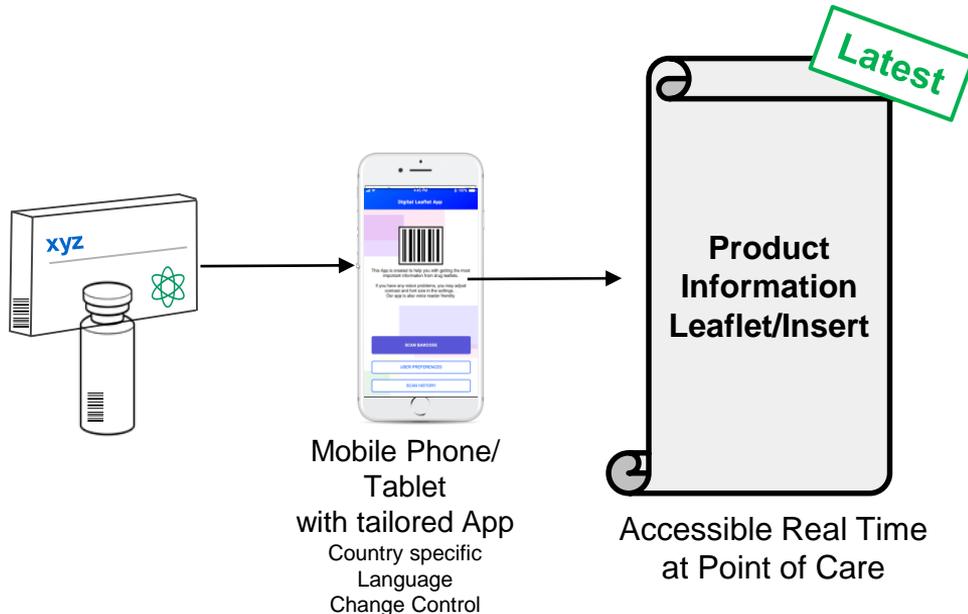
Paperless Product Information (ePI)

To provide the latest information on a medicine's safety and conditions of use

Real-time product information update to the healthcare provider and/or patient at the point of care

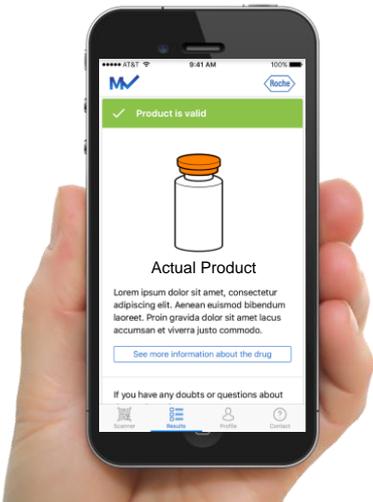
- Faster deployment of the **latest** authorized product label information: new safety consideration, expiration dating, new mode of administration
- Easier to access
- Easier to read

ePI information can flow to other systems, such as electronic health records and e-prescribing systems



Patient Safety

Verification of Product Identity

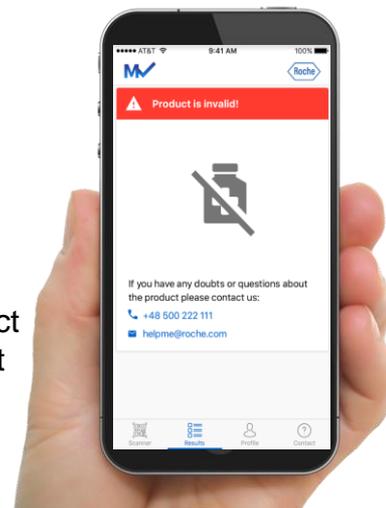


Positive Verification

- ✓ Possibility to select the criteria to be verified (SN + GTIN, **Expiration date**, etc) with country-specific information
- ✓ **The user sees basic information about the medicine & contact information**

Negative Verification

- ❖ Wrong or adulterated product
- ❖ The user is provided contact information.



Patient Safety

Track & Trace of digitized products



Product Integrity

- Identification of the product at point of care leveraging serialization (mitigation for errors & counterfeiting)
- Assurance of shipping condition within authorized parameters



Product location

- Geo-localization of the product
- Anticipating shortages
- Triggering replacement
- Adjusting distribution faster to the demand

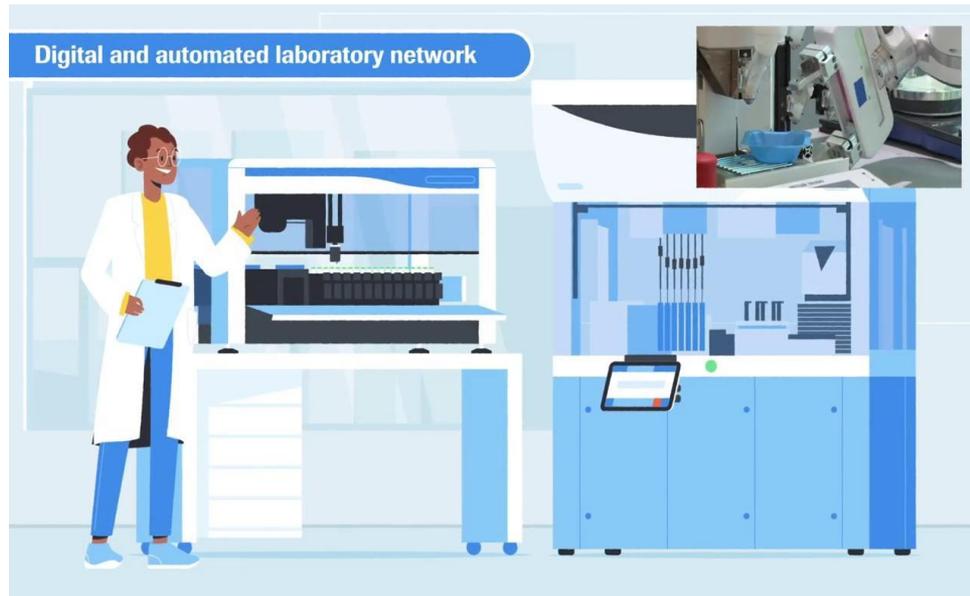


Towards a more secure and predictive supply chain and a reduction of counterfeited medicines and expired lots

New “nuts and bolts” in the Industry

How we develop the product and process understanding and enhance it

- Process automation, Robotics, Sensors
- Data: accessibility, connectivity of systems, data standards, real-time monitoring
- Documentation: Lab notebooks, automated reporting
- Knowledge management, training





“Nuts and bolts” of the Future

Data-Based Submission

Current

- e-paper submissions
- Static data shared at pre-defined stages (country specific)
- Range of data repositories



Tomorrow

- Harmonized structured data standards with global accessibilities
- Global parallel reviews or Increase reliance approach
- Rolling cloud-based data-submissions (i.e. Stability, Process Verification) with dynamic regulatory assessments
- Data analysis standards
- Other...



“Nuts and bolts” of the Future

Data-Based Submission and Cloud-Based Regulatory Ecosystem



GAIA-X

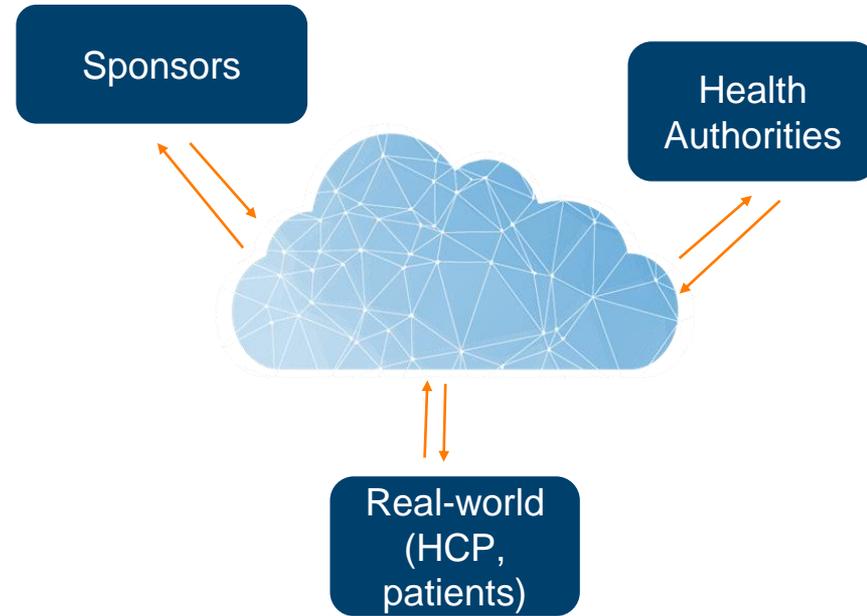
Federated Data Infrastructure for Europe

To create an open, digital ecosystem to make data available, securely collated and shared in a trusted manner



Joint venture of 10 large Pharma companies to develop a cloud submissions platform in collaboration with global health authorities

Accumulus.org



Concluding Remarks

Digital Technologies are essential to support business continuity, facilitate global collaborations and faster access to data and critical information.

In the short term, there are significant opportunities to maximize the value of digital technologies for faster access to real-time product information through e-labelling and, to ensure Product Safety around the world.

Bigger opportunities lay ahead within the regulatory field to accelerate submission & review processes, enhance transparency and collaboration... to bring innovative medicines to patients faster.

Thinking Big, Starting Small, Together



Acknowledgments

Pius Waldmeier

Stefan Blattner

Amy Mutere

Charles Morgan

Chin-Wei Soo

Judy Shimoni

Rick St John

Seth Galvarro

Mark Donahoe

Judy Fink

Gabin Wu

Rodrigo Palacios

Tricia Chean

Finny Liu

And many more...

Doing now what patients need next