Covid Lessons Learned

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“This will not be the last pandemic. History teaches us that outbreaks and pandemics are a fact of life. But when the next pandemic comes, the world must be ready – more ready than it was this time.”

-Dr. Tedros Adhanom Ghebreyesus
Director General, The World Health Organization

General Covid Lessons Learned

Time

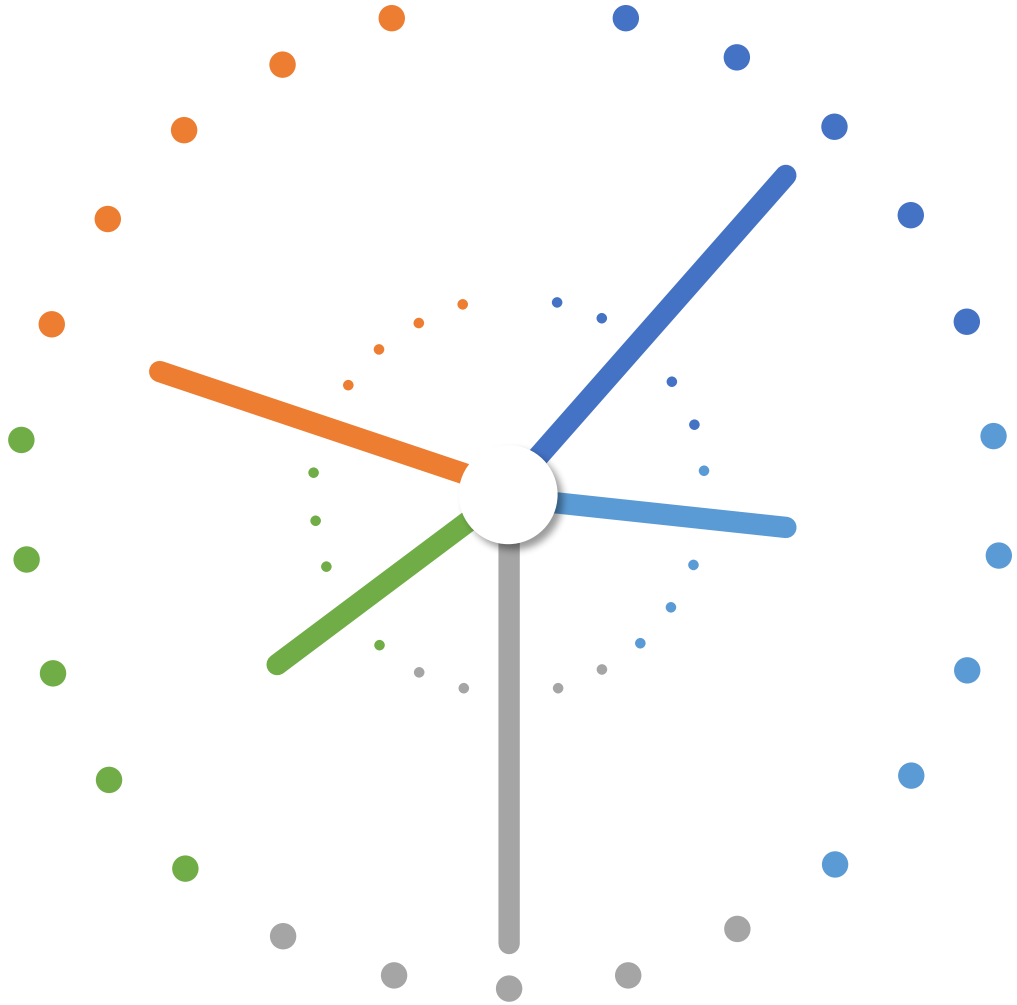
- Compressed development.
- Production scale up.
- Both in record time.
- Product modifications

Moving Target

- Access to specimans/virus.
- Divergent emergency use pathways.
- Changing templates.
- Diparity in regulation (LDTS).
- Local clinical studies/clinical testing.

Lab Capacity

- Install base.
- Training.
- Personelle.



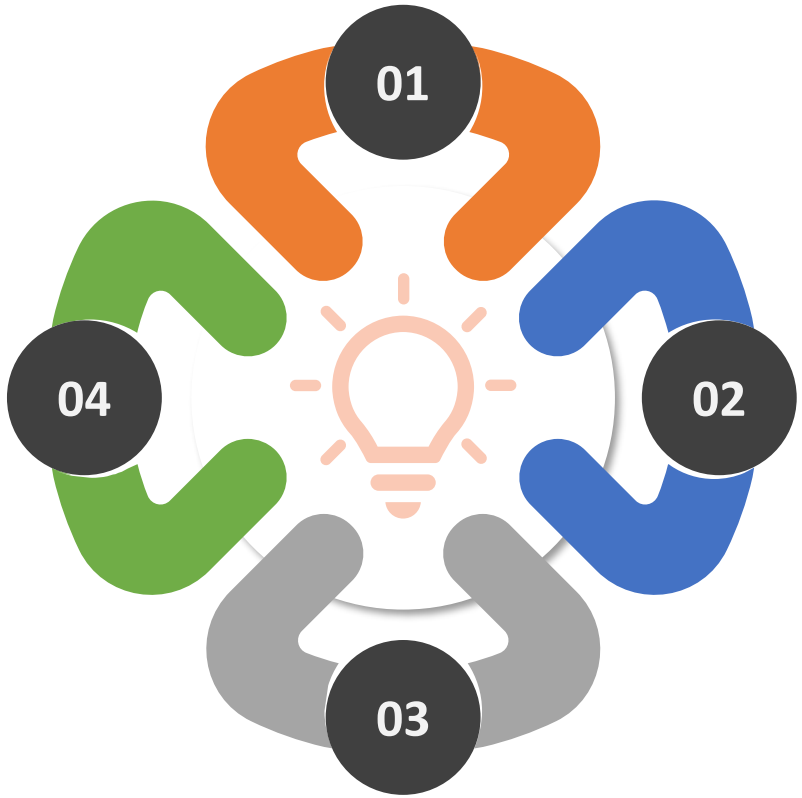
Consumables

- Availablity of consumables needed to collect specifimans and run tests.
- Supply chain.

Data Access

- Access to Real World Data/Evidence to learn real word performance and improve/evolve tests.

General Recommendations



Make Covid Lessons Learned the Norm

- Pandemic showed there are faster ways to make products accessible, without compromising quality or safety (e.g., collaboration, convergence, recognition).
- **Faster diagnosis saves human lives, allows better health outcomes, and lowers overall health care spend.**

Implement Total Product Life Cycle Reliance

- **Rely fully on the work of reference authorities**, Notified Bodies, and recognized institutions across the TPLC – this includes inspections (MDSAP* and ISO 13485).
- **Eliminate format/process requriements** that delay access without adding to patient safety.
- Implement a **harmonized, risk-based approach to product modifications** including kit size, labeling, adding a production site.
- **Limit** the need for **country specific clinical trials or testing**.

Converge and Digitize

- Pursue an **IMDRF Emergency Use Authorization Guideline**
- Adopt **internationally accepted Standards**.
- Implement **end to end electronic processes**.

Ensure Inter-Agency Alignment

- **Ensure flexibility with positive testing reporting requirements** to allow appropriate mix of lab, POC, and at home testing.

*Medical Device Single Audit Program
**TBT is a technical barrier to trade; which includes a regulatory misalignment.

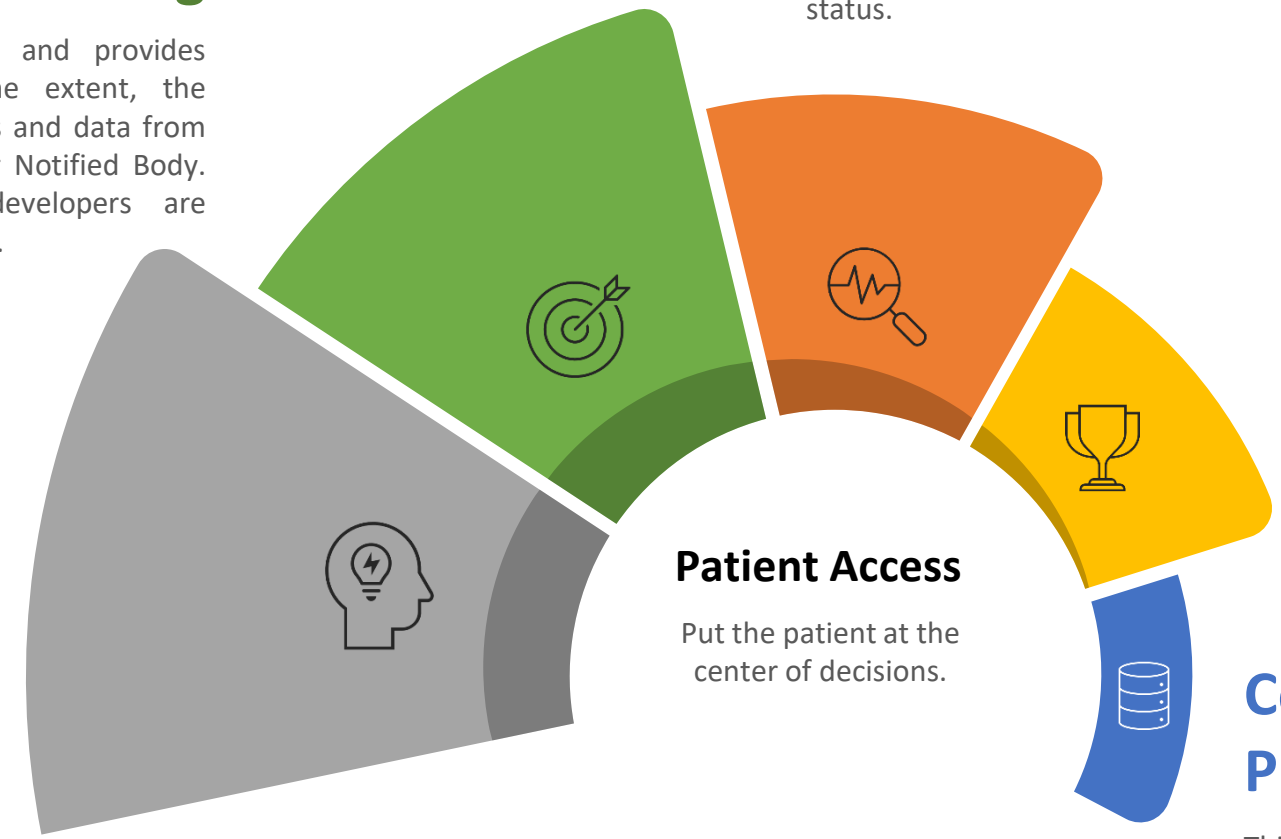
Challenges - LMIC*

Emergency Use Listing

WHO EUL listing is flexible and provides expedited access. To some extent, the program will rely on approvals and data from other reference Authorities or Notified Body. On completion of EUL, developers are expected to complete Pre Qual.

Funding

Many LMIC rely on aid funding for the purchase of medical products. In many cases, aid funding is contingent on products achieving WHO pre-qual status.



Patient Access

Put the patient at the center of decisions.

Pre Qualification

The Pre Qual program requires manufacturers to provide additional evidence and testing in order to achieve Pre Qual status.

Abridged Pre Qualification

The Abridged Pre Qual program leverages aspects of reliance and focuses on those products that have been stringently reviewed (e.g., high risk products).

Collaborative Procedure

This program allows the WHO to share results of the Pre Qualification with participating Regulatory Authorities thereby expediting access.

*LMIC means lower to middle income countries.

Recommendations - LMIC

01 Flexible Aid Requirements

- Allow jurisdictions to use aid funding for products that are **either WHO pre-qualified or approval by a Reference Agency** or Notified Body - which ever comes first.

02 Holistic TPLC Reliance Approach

- **Accept approvals** from Reference Authorities, Notified Bodies, or recognized institutions – **avoid specific formats** that add time without adding to patient safety.
- Allow developers to **select a non WHO approved lab** so long as it is accredited.
- Clarify EUL list to include **more than one brand** of the same product. Doing so will ensure adequate supply, avoid public confusion, and open access to needed medical products.
- **Expand abridged program** beyond only high-risk products.

03 Risk-Based

- Require **only significant product modifications** to be reported and approved (including to add kit sizes).
- Fully rely **on successful QMS inspection** (MDSAP, ISO 13485) to add another production site.
- Enable e-labeling, cloud submissions, and **remote inspections**.
- Ensure **strong alignment between WHO and Reference Agency** requirements. Look to IMDRF for international best practices for regulation of MD/IVDs.

Key Take Aways

- Have an internationally aligned **national policy on regulatory reliance** and implement it.
- Ensure **strong alignment between WHO and Reference Agency** requirements including standards.

Thank you!!

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Please feel free to contact me for any questions or follow up.

Doing now what patients need next