

Position paper

Regulatory agilities applied to vaccines during the COVID-19 pandemic and recommendations for the future

A focus on post-approval changes and labelling

Introduction

During the COVID-19 pandemic, National Regulatory Authorities (NRAs) and the biopharmaceutical industry applied a variety of regulatory agilities to accelerate the development, evaluation, authorization, and supply of COVID-19 vaccines. These agilities were a key factor in enabling rapid patient access to vaccines.

Experience from the pandemic and the use of regulatory agilities offers valuable insights on how regulatory systems may be adapted to further support innovation and timely patient access to vaccines at all times, not just during emergencies. This position paper outlines some key regulatory agilities implemented in areas such as research and development, regulatory evaluations, authorizations, and post-approval changes (PACs) and labelling. Key learnings and recommendations to enhance regulatory frameworks in the future are also included.

An overview of key regulatory agilities

Vaccine development and decentralized clinical trials (DCTs)

Vaccine development is usually a long, sequential process with many steps that include not only obtaining clinical evidence, but also validating the manufacturing process to ensure product purity, safety, and quality. However, during the COVID-19 pandemic, this process was successfully compressed and accelerated, relying on prior knowledge of vaccine development¹. To support rapid research and development of vaccines, NRAs prioritized authorization of studies for COVID-19 research which allowed remote monitoring of trials and reduced notification requirements for any non-significant changes to authorized trials². Agilities with respect to validation of manufacturing and lot release procedures were also exercised to the extent feasible without adverse impact to product quality.

Several activities, such as trial recruitment and monitoring, were more difficult to conduct due to the risks of virus transmission. Clinical research continued by **leveraging digital tools and increased decentralization** of clinical trials. For example, telephone and telemedicine visits facilitated recruitment and monitoring; telephone interviews and use of smartphone apps were encouraged for outcome measurements; and investigational medicinal products (IMPs) were shipped to patients' homes³.

Decentralized or hybrid clinical trials (including aspects of the traditional on-site trials and leveraging digital tools in clinical research) can advance innovation beyond pandemic times. These trials can:

- Facilitate the **recruitment, participation, and retention** of clinical trials participants, by using online informed consent and eliminating the need for patients to travel to sites.
- Ease recruitment of a **diverse patient population**, as geographical location is less of a barrier.
- Support **environmental sustainability**, decreasing the need to travel to sites.
- Allow for better **long-term monitoring** and easier collection of **real-world data (RWD)**, relying on the use of wearable devices to gather data.

Despite the benefits of DCTs, their implementation is still in evolution. For instance, DCTs often decrease or eliminate physical patient-clinician interactions which may be more important in some cases compared to others (i.e., when there might be concerns related to the vaccine administration as the vaccine has not yet been dispensed or delivered to patients). Rather than replacing standard on-site clinical trials, DCTs or hybrid clinical trials should be increasingly adopted to enhance clinical research depending on the context and should always take the patient-perspective into account.

Agilities in the evaluation and authorization of vaccines marketing applications (MAs)

Given the health emergency, NRAs successfully **accelerated processes related to the evaluation and authorizations** of COVID-19 vaccines. This was achieved whilst ensuring maintenance of acceptable standards of vaccine quality, safety, and efficacy. Key examples of agilities applied by NRAs included rolling submissions and reviews. These agilities allowed sponsors to provide data at a later stage and NRAs to start reviewing data as they became available from ongoing studies, de facto accelerating development, and regulatory approval timelines. Exceptional authorizations such as conditional marketing authorizations (CMAs) and emergency use authorizations (EUAs) were also granted and were key to accelerating access to vaccines⁴. Notably, the WHO provided recommendations for Emergency Use Listing (EUL) of certain COVID-19 vaccines. EUL is a risk-based procedure for assessing and listing unlicensed vaccines, to expedite availability in case of public health emergency⁵. Collaborative assessments were also used among NRAs to maximize efficiency in the evaluation of COVID-19 vaccines. For instance, the European Medicines Agency (EMA) OPEN Pilot facilitated the assessment of the same data by multiple NRAs⁶.

Accelerated evaluations, authorizations and risk-based procedures in regulatory decision-making should continue to be utilized (or established in jurisdictions where they do not exist) at any time for vaccines targeting high unmet needs or during health emergencies.

Increased communication and collaboration

Increased **collaboration and communication among NRAs and the industry, among NRAs, and within international fora** such as the International Coalition of Medicines Regulatory Authorities (ICMRA), helped to accelerate the development, authorization, and supply of vaccines during the pandemic.

Communication among NRAs and the industry (both individual companies and industry associations) became more frequent allowing a new level of real-time discussion and collaboration. Many NRAs also provided guidance to product developers to facilitate clinical development of vaccines. ICMRA had a key role in supporting coordination and cooperation among NRAs as well as increased efficiency in regulatory decision making to accelerate the development and authorization of COVID-19 vaccines.

Regular cooperation among different stakeholders should be incentivized, as it can increase efficiency of regulatory activities and help to save limited resources for NRAs and the industry. Particularly, when addressing public health threats such as a new virus, ensuring frameworks and processes are in place to facilitate coordination and alignment among stakeholders is crucial to efficiently address the emergency.

Use of reliance

Reliance is defined as the act whereby the NRA may consider and give significant weight to assessments performed by another NRA or trusted institution, or to any other authoritative information in reaching its own decision⁷. Use of reliance is increasingly seen as a way to make more efficient use of existing resources.

During the COVID-19 pandemic, the WHO encouraged recognition of the WHO EUL which resulted in some national authorizations of COVID-19 vaccines. This was a successful example of a reliance mechanism, allowing good use of limited regulatory resources, avoiding duplication, and accelerating patient access to vaccines⁸. Additionally, many **NRA**s **successfully relied on EUAs and CMAs** by some stringent regulatory authorities⁹.

Normally in most countries, **vaccine lot release** by an NRA or National Control Laboratory (NCL) is required in the post-licensing regulatory oversight of vaccines. This results in the batch being tested by the original releasing authority (reference NCL) in the country where the vaccine is manufactured and then tested again in the receiving countries. In normal times, release testing of vaccines can already slow down patient access to vaccines, and, in emergency times, this effect can further hinder timely access to vaccines. To expedite supply of COVID-19 vaccines, the WHO offered recommendations for batch release of prequalified vaccines or EUL according to the “WHO Operational Tool for efficient and effective lot release of COVID-19 vaccines”. Receiving countries were advised not to conduct lot release testing again on vaccines procured from assured sources - such as vaccines that are prequalified, listed under WHO EUL, or approved by stringent regulatory authorities (SRAs) - as they have been tested and released already by NRAs with stable, formal approaches for vaccine approval. To expedite the deployment of the EUL listed vaccines, the WHO thus recommended to rely on the lot release certificates issued by the responsible NCL that are provided with each batch of prequalified/EUL vaccines^{10,11}. In both non-emergency and emergency times, adoption of **batch release reliance** should be further promoted as it can help to eliminate redundant testing and accelerate supply and access to vaccines.

Use of reliance in regulatory decision-making should always be encouraged, as it can:

- Facilitate the **efficient use of limited resources** of NRAs.
- Encourage **trust and collaboration**.
- Lead to **faster patient access** to vaccines.

Moreover, widely using regulatory reliance in non-emergency times can strengthen regulatory frameworks and ensure that clear processes for efficient use of reliance are in place and that stakeholders are comfortable with using it. This can also set a good basis for maximizing the use of reliance mechanisms during emergency times.

Reliance on validated platform approaches

Finally, reliance on validated **platform approaches** - such as those posed by Messenger RiboNucleic Acid (mRNA), Chinese hamster ovary (CHO), and baculovirus, can help to advance innovation especially in emergency times. As long as these platform approaches are scientifically justified to establish relative confidence in the reliability or predictability of a specific platform, the industry should continue to explore innovative approaches to vaccine research and development (ideally already during non-emergency times) and NRAs should encourage and welcome such efforts.

Agilities related to Post-Approval Changes (PACs)

Post-approval changes (PACs), or variations, refer to specific changes or variations that a manufacturer makes to a product. PACs are necessary during a vaccine's life cycle to maintain routine production, improve the efficiency of the manufacturing processes, improve the quality control methods, or update the product labelling information¹².

Global approval of PACs is thus important to avoid supply disruption and continuously improve existing vaccines. Many PACs require approval by individual NRAs before implementation and a manufacturer may need to submit multiple applications to NRAs worldwide. Moreover, regulatory guidelines for complex biological products, such as vaccines, require significantly more documentation compared with guidelines for drugs. For this reason, regulatory approvals of PACs submissions can be lengthy, and a change can take 3 to 5 years for approval globally. This ultimately increases the risk of delaying vaccine supply and of potential vaccine shortages^{13,14,15}.

Agilities to expedite assessment, approval, and implementation of PACs

Given the rapid development process of COVID-19 vaccines, their complexity, and the need to urgently increase production and supply, manufacturers had to submit several PACs to the NRAs in the countries where their vaccines were licensed. To accelerate the assessment and implementation of PACs and allow increased manufacturing capacity of vaccines, NRAs allowed various agilities such as **prioritization of PACs reviews**, and assessments and approvals of PACs in the **absence of full data** (with certain data provided at a later date)¹⁶. For manufacturers, the ability to provide data related to time-consuming activities (e.g., stability testing, process validation) later can result in substantially faster development timelines and regulatory approvals¹⁷.

To expedite Chemistry, Manufacturing and Controls (CMC) changes, NRAs allowed **flexible approaches to CMC data requirements** such as process qualification / validation of data including concurrent validation and continuous process verification. It is important to note that agilities and early approvals, do not represent a reduction in regulatory standards, and that irrespective of the agilities applied, the dossiers are eventually completed with the full data required.

Reliance mechanisms were used by NRAs to ensure optimal use of limited resources and enable fast access to vaccines. For instance, to expedite CMC changes, many NRAs allowed reliance on assessments carried out by other NRAs or participation in joint assessment programs¹⁶.

Agilities were also applied to good manufacturing practice (GMP) **inspections**. For facility assessment in lieu of inspection, some NRAs allowed remote interactive assessment, desk-based review of documents, and review of inspection reports by other NRAs via a Mutual Recognition Agreements (MRA) or Confidentiality Agreements – constituting another example of use of reliance. MRAs and Confidentiality Agreements can be beneficial in both non-emergency and emergency times. Moreover, to maximize preparedness for emergencies, these agreements should ideally be set up before an emergency occurs.

The International Council for Harmonisation (ICH) Q12 defines the **Post-Approval Change Management Protocol (PACMP)** as a description of specific changes that a company would like to implement during the product lifecycle and how these would be prepared and verified. This allows early evaluation of the change strategy to enable planning of future change(s) by the applicant during the lifecycle of a product¹⁸. PACMPs allow manufacturers and NRAs to agree upfront on the data required to support a future change, enabling manufacturers to act quickly to implement changes which can be facilitated by lower reporting categories¹⁹. Successful examples of the use of PACMPs were recorded during the pandemic. For instance, the EMA, leveraged PACMPs (and prior knowledge) to speed up the manufacturing process and add three extra manufacturing sites within one week of submission compared with a minimum standard of more than 60 days¹⁷. PACMPs however, do not exist in many countries²⁰.

Recommendations for optimal post-approval changes (PACs) management

The COVID-19 pandemic experience highlighted the importance of increasing efficiencies in PACs management, for instance via use of reliance and risk-based approaches, to accelerate patient access to vaccines in both non-emergency and emergency times²¹. The following recommendations can help to further advance innovation and avoid disruption to the supply of quality-assured vaccines at any time.

- **Ensuring a widely shared understanding of risk-based approaches as well as regulatory convergence of PAC requirements**, in relation to classification and timelines for instance, would be highly beneficial to ensure clear procedural guidance for PACs and an efficient PACs management system for all stakeholders²¹.
- NRAs should increasingly consider **using reliance** to ensure efficient use of resources and accelerate PACs approvals, as appropriate. The role of international bodies such as the ICMRA, International Conference of Drug Regulatory Authorities (ICDRA) and the WHO in promoting collaboration, reliance, and related best practices, will continue to be fundamental as we move out of the COVID-19 pandemic.
- **Alignment with international guidelines and standards**, such as the ICH Q12 guideline²² and the WHO guidelines on procedures and data requirements for changes^{23,24}, would help to achieve regulatory convergence. For instance, maximum review periods for changes should follow the WHO guidance (for major changes, a maximum of six months review; for moderate changes, a maximum of three months review; and for minor changes, only require a notification to the NRA)²¹.
- **Following the ICH guideline** can help the industry to manage CMC changes effectively under the company's Pharmaceutical Quality System (PQS) with less need for extensive regulatory oversight prior to implementation. The ICH Q12 guideline demonstrates how increased product and process knowledge can contribute to a better understanding of which PACs require a regulatory submission as well as the definition of the level of reporting categories for such changes. For instance, high-risk changes are categorized as prior-approval, requiring regulatory authority review and approval prior to implementation; moderate- to low-risk changes are communicated to the regulatory authority as a formal notification, occurring within a defined period before or after implementation, according to regional requirements¹⁴. Furthermore, for rapid benefit of ICH Q12, the **PACMP** should be implemented as it allows an appropriate lower reporting category to enable the reporting of results after executing the protocol as agreed with the NRAs²¹.

All the above-mentioned recommendations would enable a **more harmonized and efficient PACs management framework**, reduce the regulatory burden on both industry and NRAs, support timely patient access to quality-assured vaccines and reduce vaccine shortages. However, in emergency contexts, such as a pandemic, when the number of PACs to manage in a short timeframe increases, close collaboration and communication among industry and NRAs should be maximized, review of PACs should be accelerated, risk-based approaches to decision-making should be implemented, and use of reliance should be maximized.

Agilities related to Labelling

Comprehensive and clear labelling is key to communicate information of vaccines to both healthcare professionals (HCPs) and patients and ensure the safe use of vaccines. Before distributing vaccines, labels must be approved by NRAs. Similarly, whenever changes to the vaccine information are required, in relation to warnings or instructions for instance, the label must also be updated.

Labelling and packaging of vaccines is subjected to individual NRAs and in-country regulations, such as language requirements, which might limit the interchangeability of global vaccine supplies, resulting in some vaccine allocations that can only be used in certain countries²⁵.

Exemptions and waivers for labelling

During the COVID-19 pandemic, NRAs allowed various agilities related to labelling and packaging requirements which facilitated the supply and distribution of vaccines. Printed labels and packages adopted for a specific market can take a long time to be approved and then produced. Proposed agilities to address this problem during the COVID-19 pandemic included **extending the implementation time of the labelling update** (except for significant safety updates), allowing **non-local language labelling, electronic submissions** of packaging and leaflets instead of physical samples, and **packing down** of larger packs of medicinal products for distribution²⁶. **Derogations to labelling requirements** were also allowed to expedite CMC changes¹⁷.

EU Member States for instance, agreed to grant a temporary exemption from the obligation to provide the printed packaging and package leaflet components in their national language, so that outer and immediate labelling for COVID-19 vaccines could be printed in **English only**. Moreover, applicants could **omit the inclusion of the package leaflet in the outer carton** to speed up the deployment of COVID-19 vaccines (although they had to distribute the printed package leaflet containing the full authorized information alongside the supplies of the vaccine)²⁷.

Agilities related to language and labelling during the pandemic were considered particularly valuable by the industry to facilitate continued patient access to vaccines. However, it was noted how the **lack of harmonization** between the approaches of the EU Member States, can limit the value of such agilities and should be addressed to maximize the agilities' potential in the future²⁸.

The International Nonproprietary Names (INN) nomenclature allows to assign unique names to pharmaceutical substances to ensure their global recognition and to facilitate identification²⁹. Any changes to a vaccine ingredient sequence requires a new INN. During the pandemic, vaccine manufacturers had to re-design their vaccines to improve protection against new variants of concern (VOC) of the virus. According to the WHO INN Working Document 21.520 of April 2021, to highlight the close relationship of a variant COVID-19 vaccine substance to the original vaccine active substance, the INN of the variant substance would be linked to the original INN by the addition of a short 2–3 letter syllable as a prefix to the original INN (this was to apply only when changes were made to the COVID-19 vaccine substances to direct the immune response to a VOC, and where NRAs were likely to authorize the variant vaccine by an abbreviated procedure. Any other change to the structure of the active substance, would be assigned a new INN)³⁰. The INN assignment process was also accelerated so that the INN for the variant vaccine substance could be incorporated into packaging and labels as soon as a variant vaccine was ready. Moreover, the review of a request for an INN for a variant COVID-19 vaccine active substance and the decision-making processes for it was also expedited.^{29,30} In case of future pandemics, processes for establishing INN should ideally be streamlined as much as possible to maximize timely access to much-needed vaccines. Granting INN exemptions could also be considered if the stakeholder community can identify alternative and agile ways to facilitate the global identification of vaccine active substances.

Electronic-labelling (e-labelling) and use of quick response (QR) codes

Printing labels and making changes to labels can increase the risk of delays to the supply of vaccines and slow down access to vaccines. Particularly during the COVID-19 pandemic, labelling and leaflet information had to be developed and updated swiftly. Not only printing labels is normally a resource intensive activity for manufacturers, but package leaflets can also rapidly become outdated and no longer contain the most up-to-date approved information.

Electronic-labelling (e-labelling) was allowed during the pandemic by several NRAs to minimize delays caused by printing and to facilitate the rapid supply and access to vaccines. E-labelling helps to provide up to date NRA approved information on vaccines, to avoid access delays and to easily share labelling between countries. E-labelling can generally facilitate the provision of information in multiple languages on additional clinical data, safety information, and extending expiry. This can allow manufacturers to distribute finished products swiftly to any market²⁵. E-labelling regulations are currently being adopted at different paces by NRAs worldwide. In Japan, for instance, e-labelling has advanced considerably over the last few years, and it is set to completely replace paper labelling in July 2023³¹.

Quick Response (QR) codes were used during the pandemic to provide access to electronic versions of product information³². EU Member States agreed for instance to temporarily accept the omission of the printed country-specific Blue Box information which could be provided via a QR code. EU member states also allowed the provision of translations of the package leaflet in their national language(s) via a QR code, as an additional means to access statutory information³³.

Recommendations to enhance labelling of vaccines

The COVID-19 pandemic has further accelerated the use of digital tools and has shown how labelling agilities can effectively support a resilient supply chain for vaccines and help to avoid drug shortages. Implementation of some agilities, such as waiving labelling requirements and allowing for single language labels, should be promoted in emergency contexts, for instance during pandemics or when dealing with vaccines targeting high unmet needs within the population.

Other agilities however, such as e-labelling and use of QR codes, should be gradually adopted globally. For vaccines administered in hospitals, a quicker shift to e-labelling could already be envisioned, with a printed label provided on request. During a transition period to a full digital label, paper leaflets could still be included in the vaccine packaging with a note that an electronic version for the most up-to-date information can also be consulted.

QR codes can help to provide quick access to electronic versions of printed information, such as leaflets and labels, or to provide access to supplemental information that it is not physically present on the package e.g., such as updated product information, information on expiration, or additional translations of leaflets.

E-labelling has the potential to:

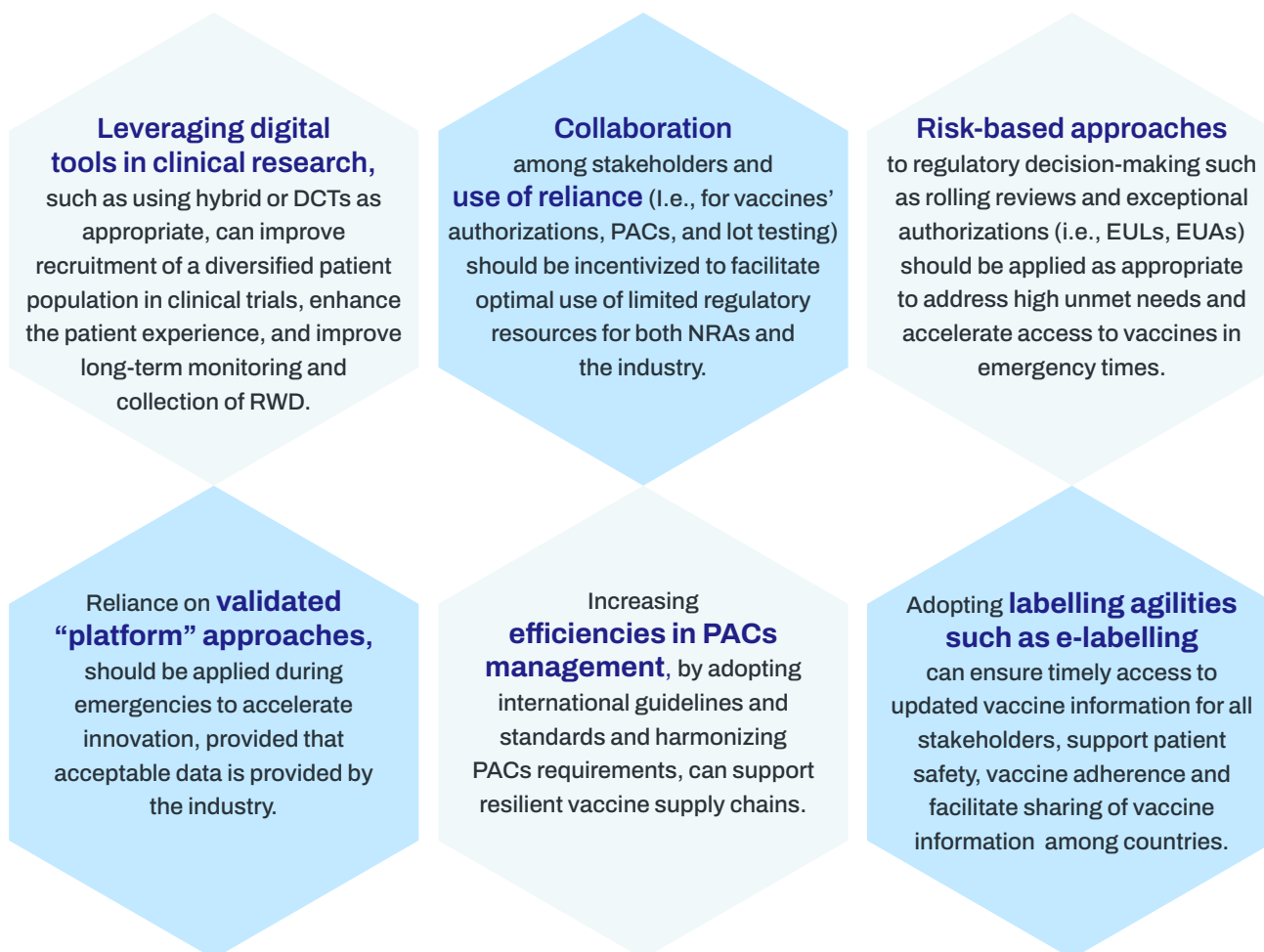
- Simplify and accelerate **regulatory information management**.
- Facilitate access to the most **updated information** at any time for all stakeholders, including NRAs, HCPs, and patients.
- Help to reach **environmental sustainability** by decreasing the need for printing.
- Contribute to increase **patient safety**, by providing up-to-date information approved by the NRAs in real time and alerts about important vaccine changes.
- Increase **vaccines adherence**, by facilitating patient understanding.
- Offer access to the various regulatory approved **translations** of leaflets and labels that might be available in the preferred language by stakeholders.
- Improve **readability** giving the possibility to adapt font size.
- Facilitate **sharing of information** among stakeholders including families and caregivers^{26,31}.

Conclusion, key learnings, & recommendations

Conclusion

To support the accelerated development, evaluation, authorization, and supply of vaccines to address the COVID-19 pandemic, NRAs successfully adopted a variety of regulatory agilities. All stakeholders have an opportunity to reflect on the lessons learnt from this recent experience which can help to enhance regulatory systems, in both non-emergency and emergency contexts. The stakeholder community should continue to engage in dialogues to establish a shared way forward to enhance regulatory frameworks and support innovation and timely patient access to vaccines. Multi-stakeholder workshops, including members of NRAs, industry representatives, and potentially members of key organizations such as ICMRA, ICDRA and WHO, can allow participants to share experiences and challenges related to the use of key agilities, such as those related to PACs and labelling, and facilitate alignment on recommendations for their future adoption. Adopting agilities in regulatory decision-making can facilitate timely development, evaluation, supply, and access to safe and quality-assured vaccines at all times. The adoption of regulatory agilities in non-emergency times may also increase overall stakeholders' confidence with using agilities. This, and having established emergency frameworks, can contribute to enhancing preparedness for the next pandemic, reducing uncertainty, avoiding impasses, and ensuring that all stakeholders are able to act promptly to address the emergency and facilitate accelerated access to much-needed vaccines.

Key learnings & recommendations



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