



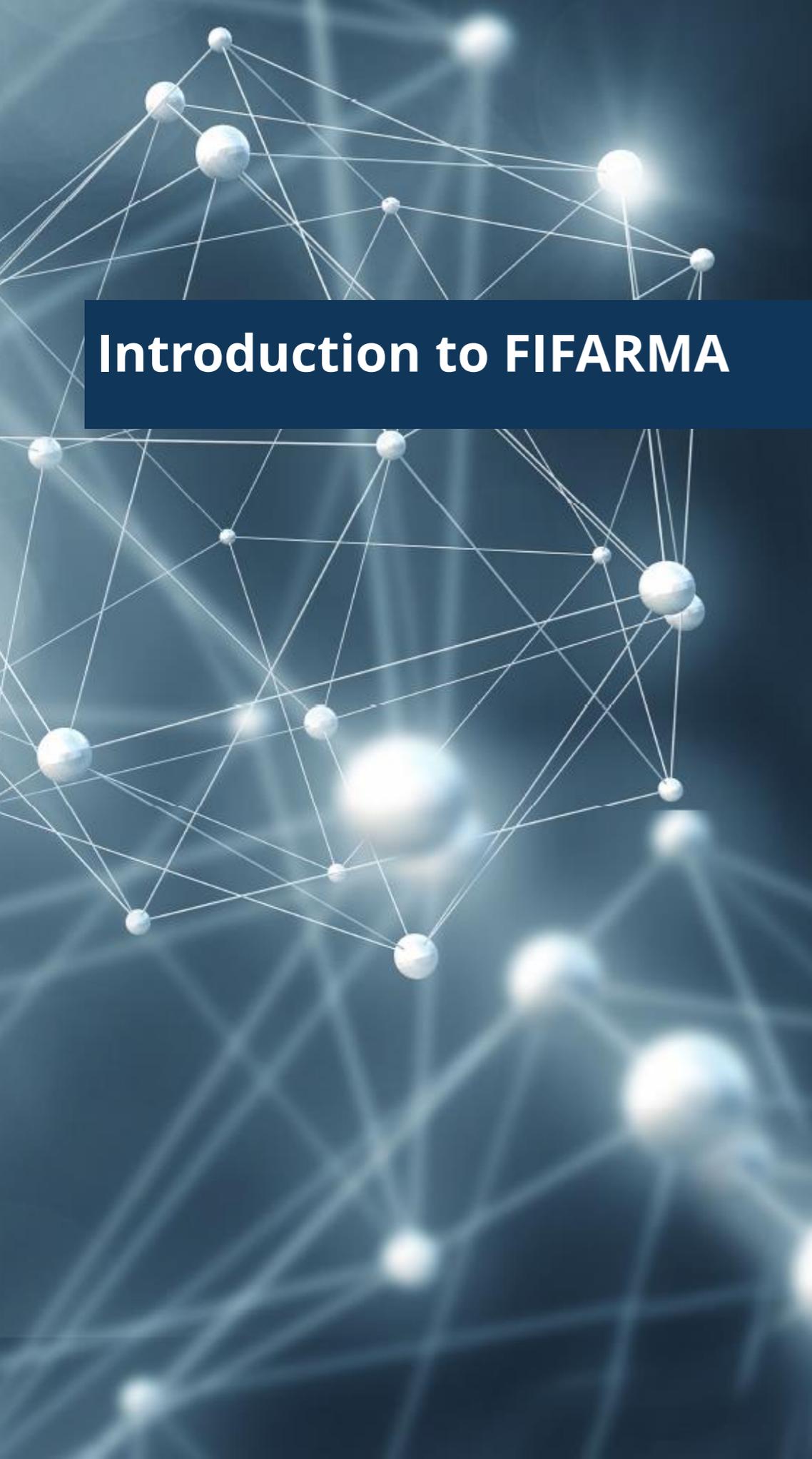
Regulatory Issues in the Context of Health Emergencies – Learnings and Recommendations

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FIFARMA



Introduction to FIFARMA

FIFARMA is the **voice** of all companies and associations of the pharmaceutical R&D industry in Latin America and the Caribbean

FIFARMA **improves** health in Latin America fostering the development of patient centric health policies

FIFARMA holds permanent **communication** with health stakeholders in the region including health authorities

FIFARMA currently **represents** 15 multinational companies and 11 Local Associations from the pharmaceutical R&D industry

What we do

We bring the Latin American & Caribbean research & development (R&D) biopharmaceutical industry and the health community together to shape health policies that prolong, preserve and improve life for patients.

How we work

We promote dialogue within our industry and in close collaboration with intergovernmental bodies, non-governmental organizations, health authorities and civil society organizations to bring value to society by advocating for sustainable health systems with high regulatory standards and ethical principles and offering longer and better lives to patients.

FIFARMA: Regulatory Priorities in a pandemic



Working with the NRAs to define science-based regulatory strategies to ensure the availability of medicines and vaccines for COVID-19

Maintaining supply of non-COVID-19 medicines and vaccines.

Ensuring all our medicines and vaccines continue to meet appropriate standards for quality and safety.

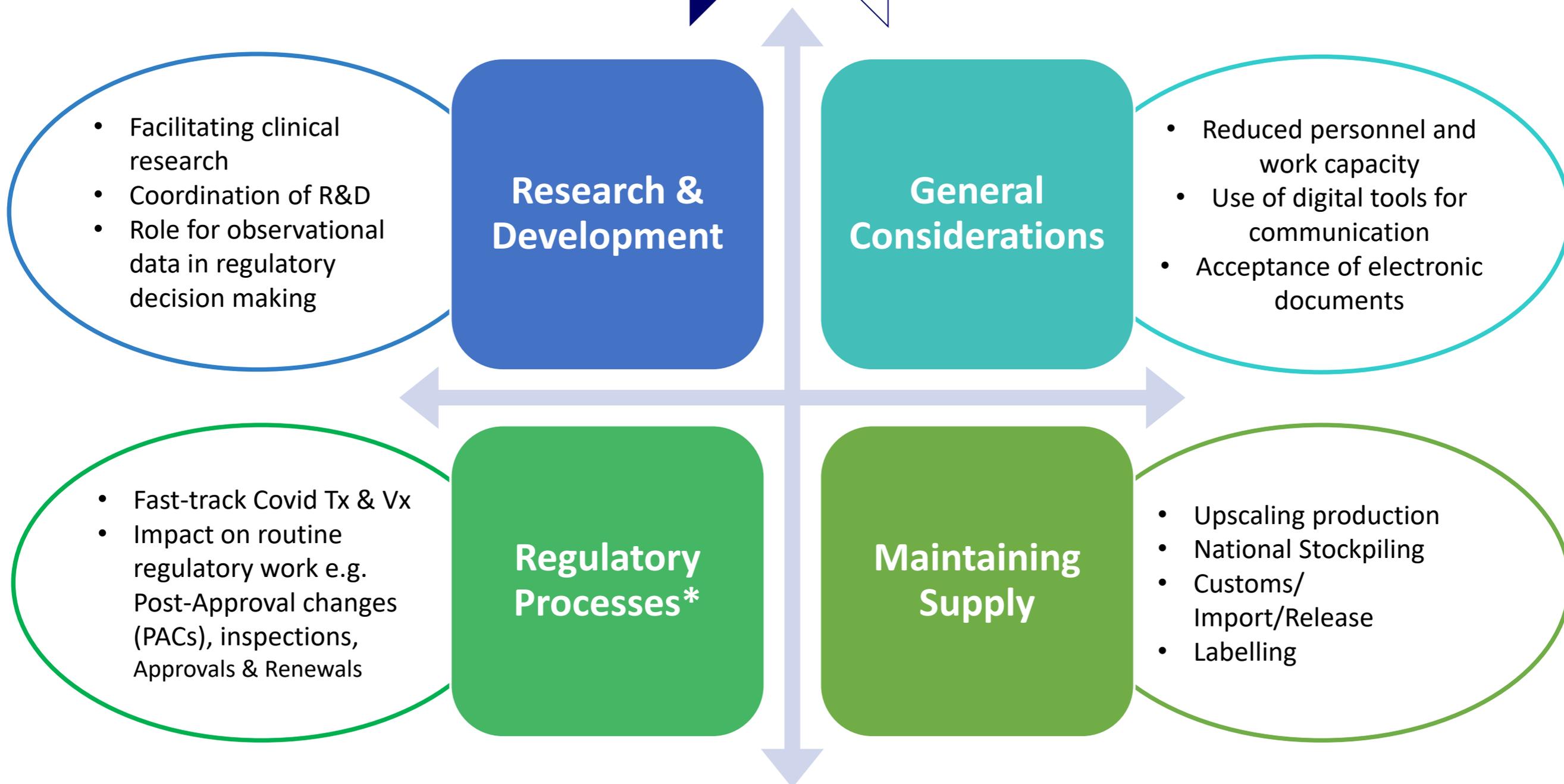
Progressing research into new treatments and prevention of COVID-19 and of other conditions.

A shared challenge



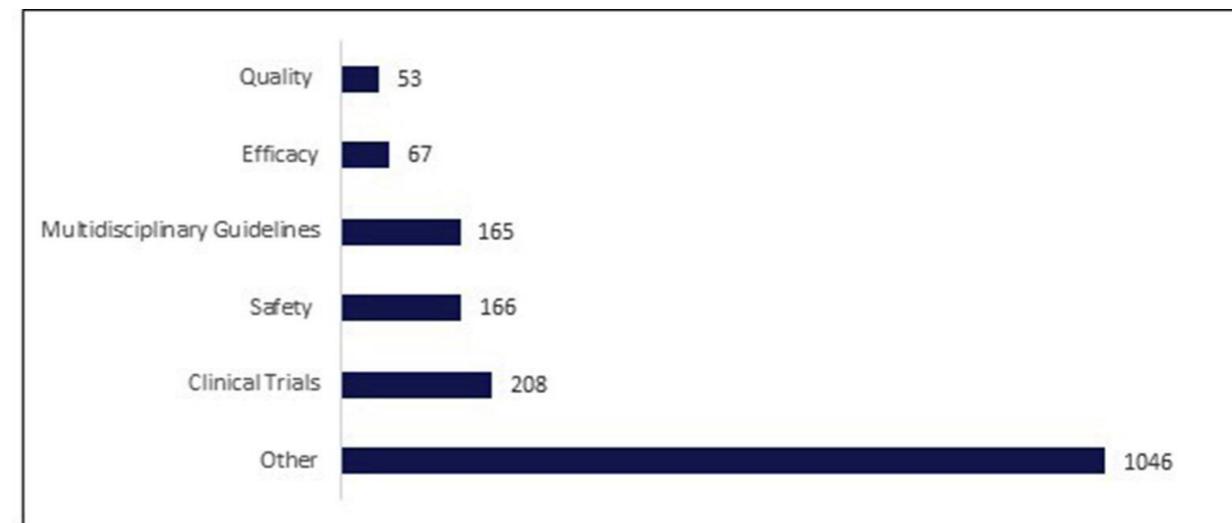
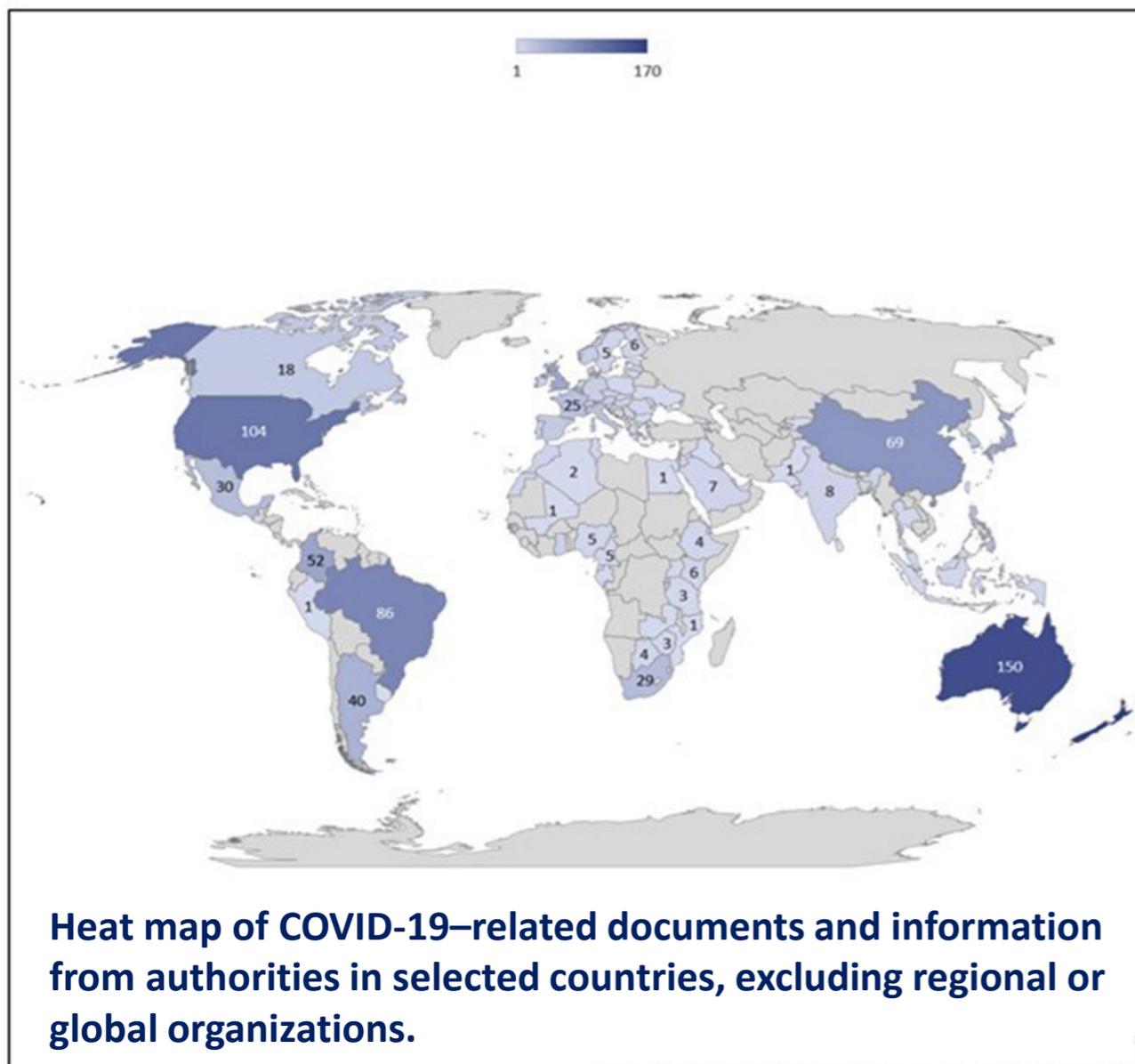
Industry: Maintain regulatory compliance of Medicinal products, Devices, Clinical Research (Across multiple NRA)

National Regulatory Authority: Maintain regulatory oversight of Medicinal products, Devices, Clinical Research (Across multiple products)



*Product Registrations, Renewals, Lifecycle Management, Inspections, Post-Market Surveillance

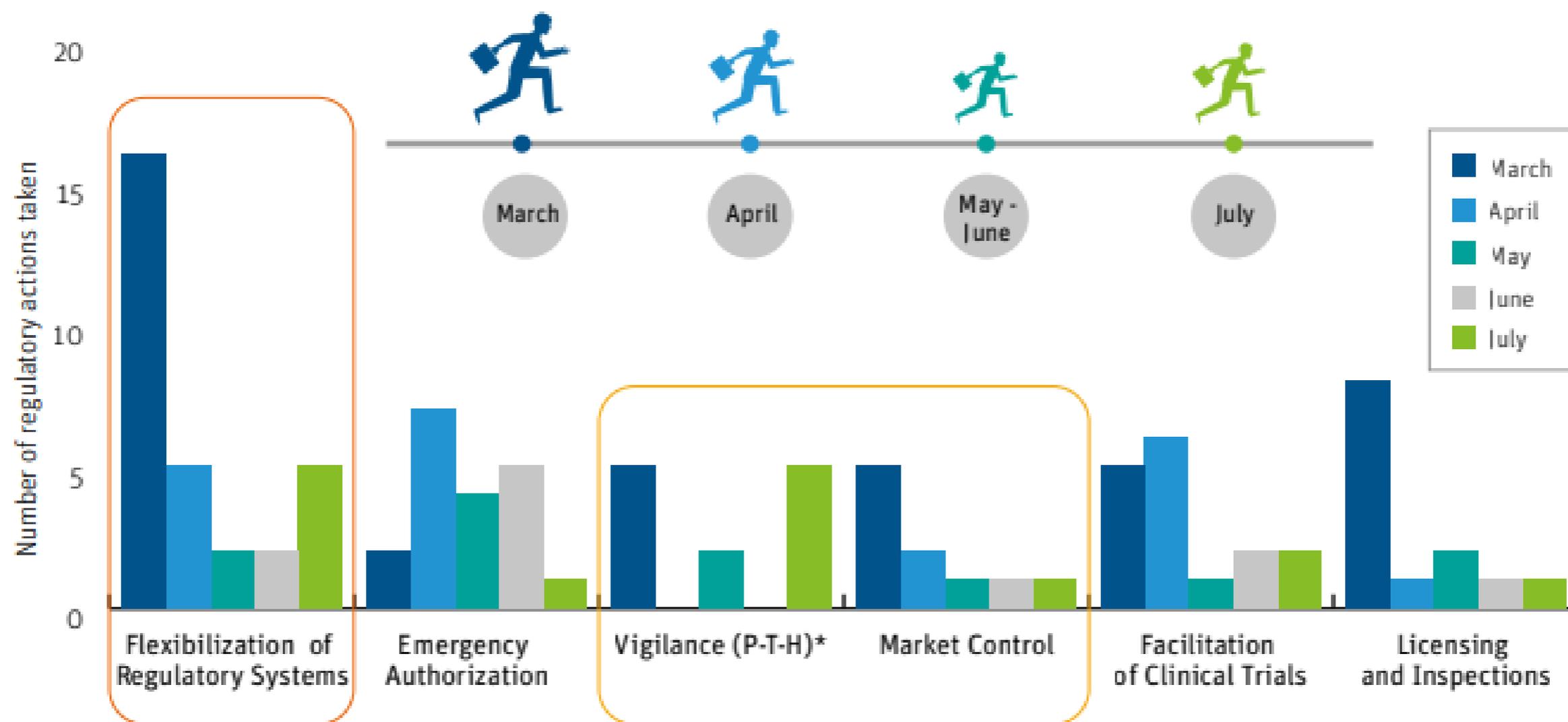
Global Agilities



Number of COVID-19-related documents and information, by topic area.
 Other = documents or information that could not be classified elsewhere (eg, agency operation and continuity, procurement, data protection, coordination mechanisms and platforms, meetings and response documents, among others).

NRA Emergency Response in Practice – Initial Actions

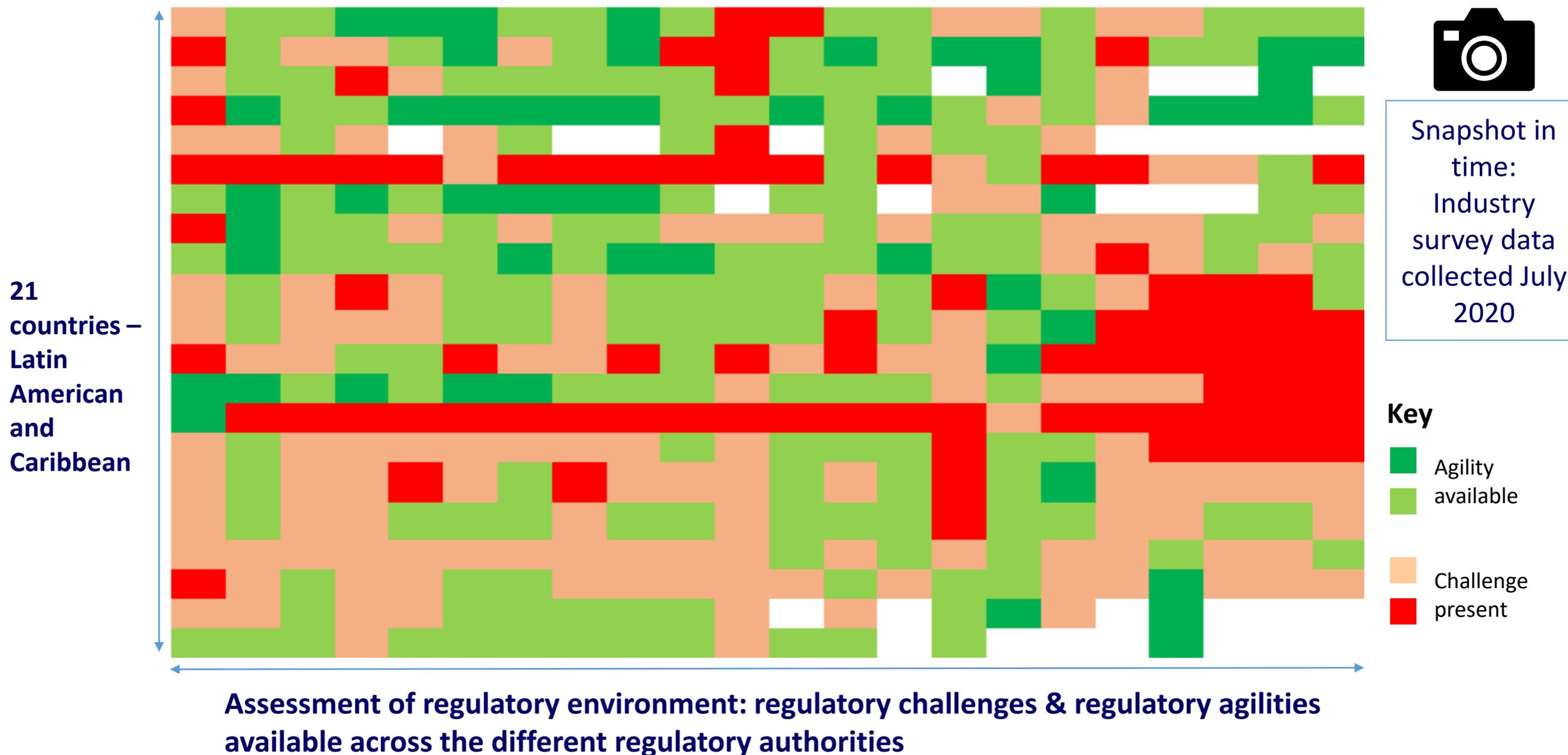
Figure 9.1. Latin American NRAs regulatory trends overview from March to July 2020



Notes: * P-T-H: Pharmacovigilance, technovigilance, and hemovigilance. The figure shows the areas in which regulatory actions are categorized. Each bar represents a month and despite the fact that regulatory actions are usually sustained over time, this helps to visualize where efforts are concentrated. Most of the regulatory actions focus on the relaxation of regulatory requirements. Areas such as market surveillance and control are those that have had less prominence. It can also be observed that most of the regulatory actions were taken in March and that in July there is an increase in the measures related to surveillance.

Source: Analysis performed using the regulatory actions shared by NRAs with PAHO through a common repository established during the emergency in the Regional Platform on Access and Innovation for Health Technologies (PRAIS).

Heat map – Regulatory challenges & agilities during current Health Epidemic



Navigating a rapidly changing environment



Open dialogue and communication with Stakeholders

NRA decisions became more critical and visible during the epidemic. Regular, high level meetings between NRA and Industry associations allowed rapid discussions on new emerging risks for the operation of the respective Regulatory Systems.

Clear, public and transparent communications promoted regulatory compliance.

PAHO: Best Practices and Efficiencies during emergencies

“The ongoing experience with COVID-19 highlights a number of potential best practices and efficiencies for regulatory action during emergencies, even though COVID-19 is unique in terms of its pervasiveness and duration of threat.”

These best practices and efficiencies appear to include the following:

- **Flexibility in regulations and processes.** Numerous NRAR actions point to the need to be flexible in emergencies, including by having up-to-date policies and procedures, such as emergency use authorization and extension of certifications and periods of validity, etc.
- **Virtual strategies.** NRAs have taken advantage of modern modes of communication such as through use of virtual documentation and the conduct of work in virtual formats.
- **Faster timelines** Faster timelines for regulatory processes are important, and examples include expedited review of clinical trial applications.
- **Prioritized resources for emergency efforts.** Latin American NRAR have focused their efforts on 24/7 operations, including prioritization of regulation of emergency-related products.
- **Learning and information sharing.** Agencies continue to learn much from what other agencies are doing, including through information exchange.
- **Communications.** Enhanced communication with stakeholders is an essential aspect of emergency response. This includes communication with the public to provide accurate and up-to-date information, with the industry to understand new developments or potential shortages, with academia to identify much needed expertise, and with local or international government representatives to coordinate emergency actions.
- **Reduction of duplication of efforts.** The increased use of reliance to respond to the ongoing COVID-19 pandemic is worth carefully considering to increase regulatory efficiency, such as in GMP inspections

Recommendations

“Regulatory strengthening measures implemented during the COVID-19 pandemic can enhance regulatory systems more broadly beyond the current health emergency”[†]

Current Challenges

Temporary agilities ending
 Routine operations restarting
 Post-pandemic commitments due
 NRA capacity is a factor

Reliance & Good Regulatory Practices
 On-going convergence
 Sharing of ‘best practices’ globally and within the region

Proposed solutions

[†]O'Brien J, Lumsden R, Macdonald J. Strengthening regulatory systems for medicines in a changed world: where do we go from here? *BMJ Global Health* 2021;6:e004680. doi:10.1136/bmjgh-2020-004680

Best Practices: Digital Tools as a Solution

Change in ways of working



Face to Face meetings



Virtual meetings



Paper submissions



Digital Submissions



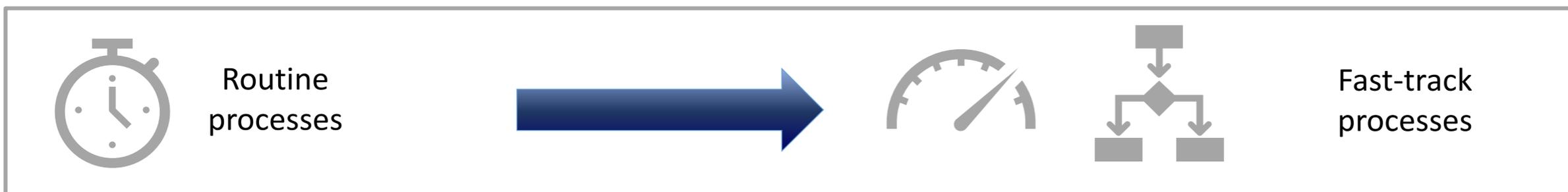
“Wet” signatures



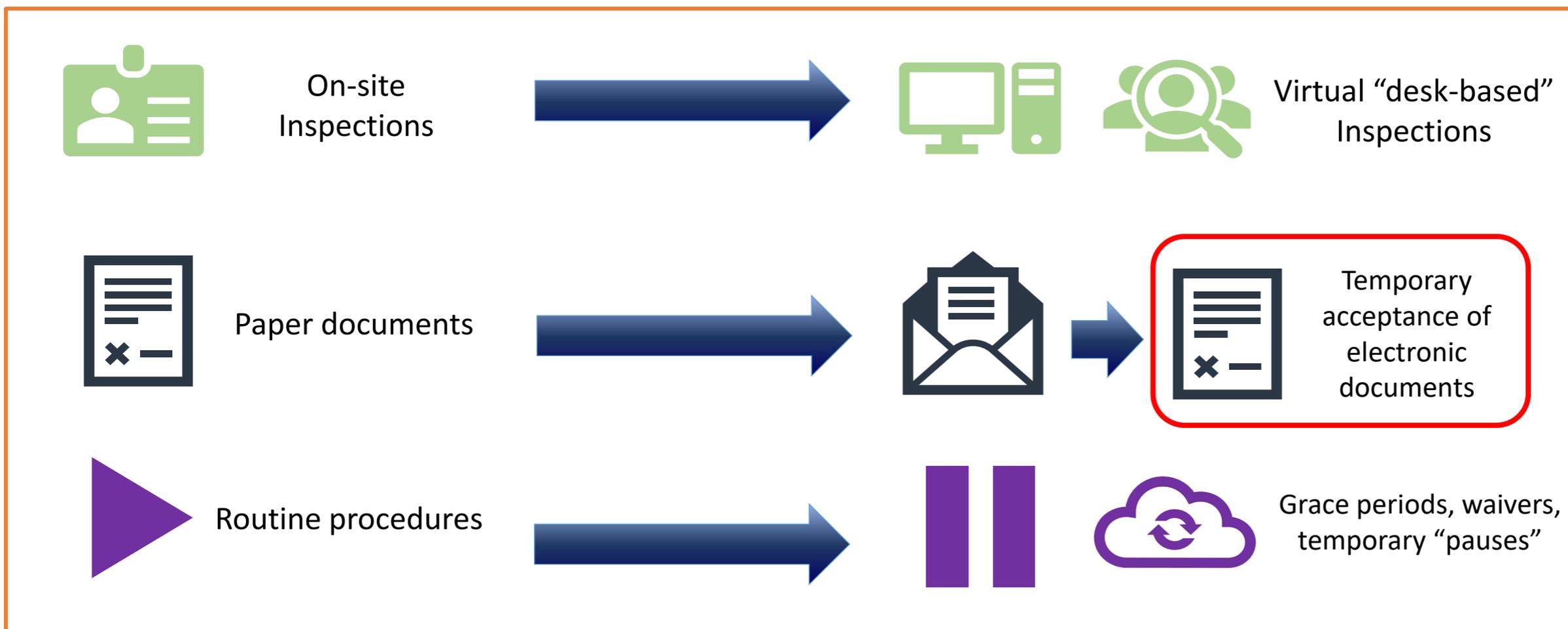
“Digital” signatures

Best Practices: Implementation of “risk-based” agilities

Fast-track Covid-19 Therapeutics & Vaccines



All Medicinal Products



Could this be permanent?

Best Practices: Maintaining Supply

Change in ways of working



Customs procedures/
Lot testing & Local
release



Fast-tracked Customs
procedures & local
release. Reliance for
testing/sample
management¹

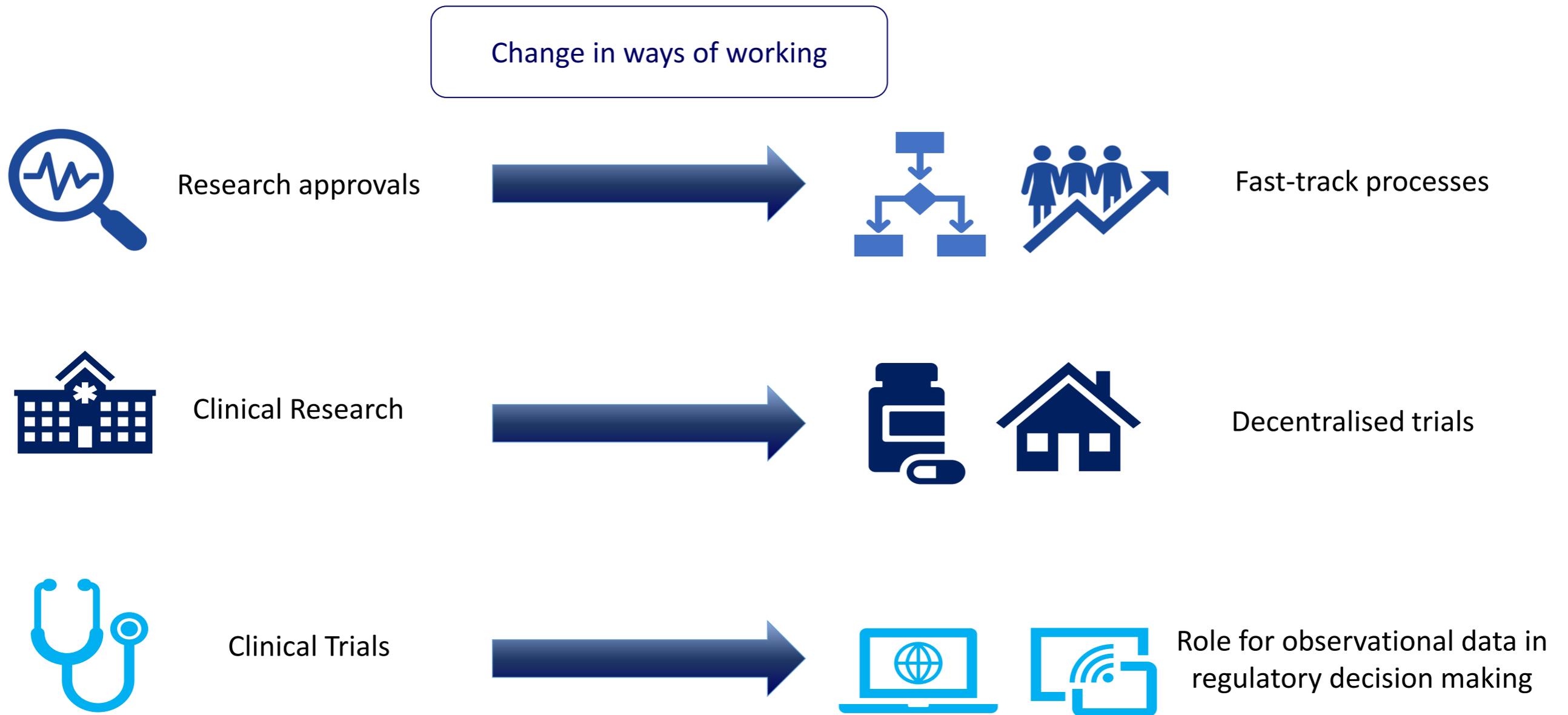


Labelling



Acceptance of
multi-country
packaging
ePI

Best Practices: Research & Development



Final thoughts



Open dialogue and communication with Stakeholders

Regular, high level meetings between NRA and Industry associations will allow rapid discussions on ongoing or emerging risks for the operation of the respective Regulatory Systems.



We are all partners in ensuring patients continue to access safe, effective and high-quality medicines.