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Regulatory Sandboxes – Developments in the EU

Nada Alkhayat – European Commission, DG SANTE, Unit D3

25 September 2023

European Commission

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OVERVIEW

1. Brief background on the EU's proposed AI Act
   - 1.1 State of play
   - 1.2 Risk classification
   - 1.3 Summary of requirements
2. Regulatory Sandboxes
   - 2.1 Key features
   - 2.2 Operation of the sandbox
   - 2.3 Re-use of personal data

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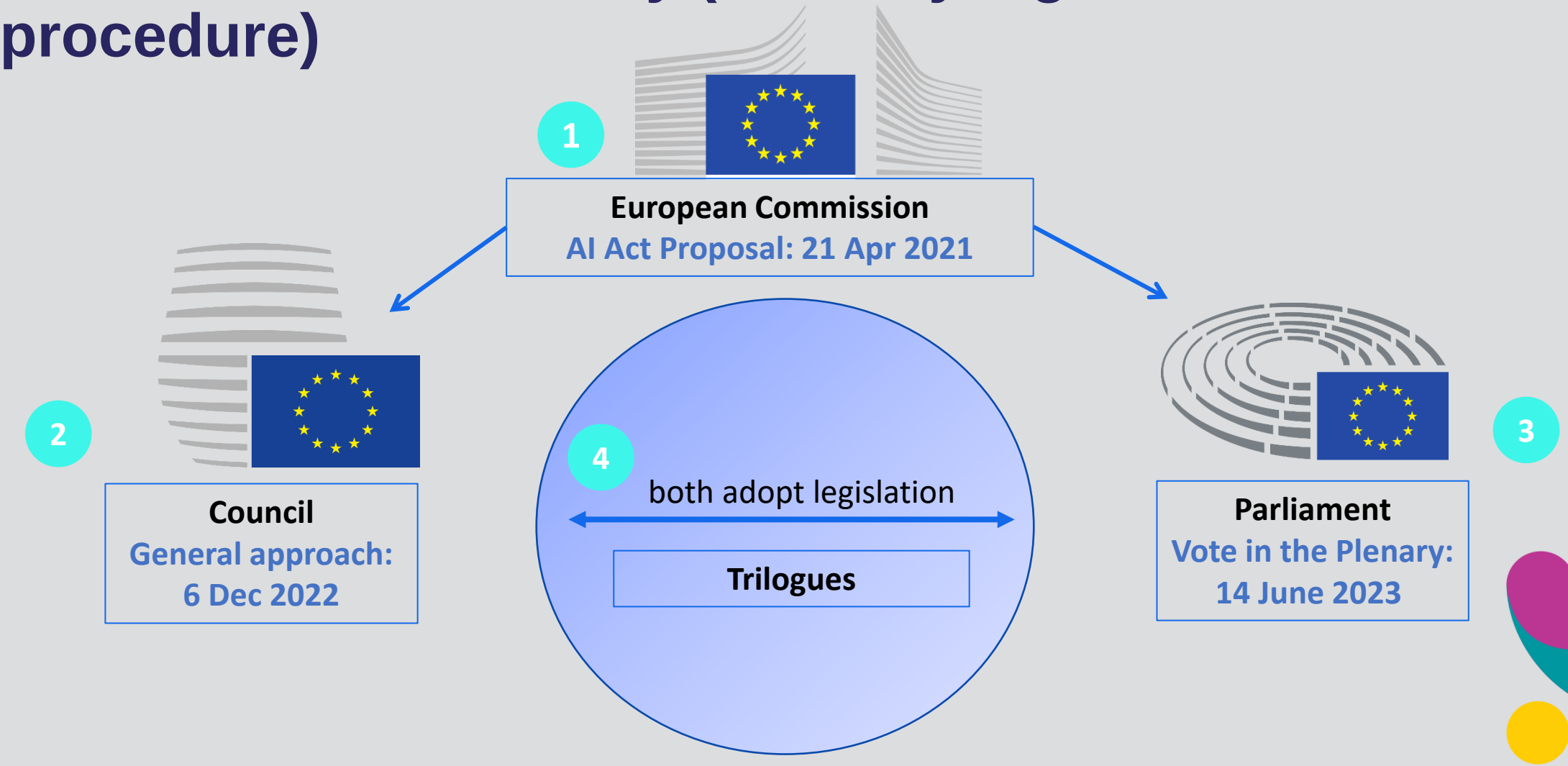
1. Brief background on the EU's proposed AI Act

1.1 AI Act: State of Play (ordinary legislative procedure)



1.2 Risk-based approach

Parliament & Council agree

*Not mutually exclusive

Unacceptable risk
e.g. social scoring by public authorities, harmful manipulation, real-time RBI for law enforcement (with exceptions)

Prohibited

High risk
e.g. recruitment, medical devices

Permitted subject to compliance with AI requirements and ex-ante conformity assessment

'Transparency' risk
'Impersonation' (chatbots), deep fakes, emotion recognition and biometric categorisation

Permitted but subject to information/transparency obligations

Minimal or no risk

Permitted with no restrictions, voluntary codes of conduct possible

1.3 Requirements for high-risk AI – including medical devices (Title III, chapter 2)

Parliament & Council agree

Establish and implement an iterative **risk management** process (identify & mitigate risks)

- Use high-quality **training, validation and testing datasets** Implement **data governance procedures**
- Establish **documentation** in Annex IV and design the system with **logging** features (traceability & auditability)
- Ensure appropriate degree of **transparency and interpretability** of the system by design & provide users with **information** (on how to use the system, its capabilities and limitations, potential risks etc.)
- Enable **human oversight** aimed to minimize residual risks (measures built into the system and/or to be implemented by users)
- Ensure **robustness**, **accuracy** and **cybersecurity** throughout the lifecycle

NB! Harmonised technical standards developed by ESOs will support providers to demonstrate compliance.

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2. Regulatory Sandboxes

Articles. 53 and 54 of the AIA

2.1 Key features of AI Regulatory sandboxes

Regulatory supervision

- Development under the direct supervision and guidance of regulators

Pre-marketing phase

- Testing under real conditions possible, but in controlled environment

Objective to ensure compliance

- With AI Act but possibly also GDPR and sectoral laws (in a single sandboxing project)

Of specific AI projects

- AI systems must be 'innovative' for the market

Variety of possible participants

- Public or private

2.3 Operation of the sandbox

- Can be utilised in the **pre-market phase and re-assessment** by the provider/user in case of substantial modification to certified AI systems
- **No derogation from the AI requirements/conformity assessment**
  - But clarity and margin of discretion how regulators apply them to specific AI use cases/projects
- **Uniform conditions for the operation: EU implementing acts**
  - Eligibility criteria
  - Procedure for application, selection, participation and exiting from the sandbox
  - Rights and obligations of the participants
  - General provisions and (potentially) sectoral ones

a) Prevent market fragmentation
b) Level playing field
c) Flexibility *(can be adapted)*

2.4 Special regime for re-use of personal data in the AI regulatory sandbox – art. 54

- Provides **a legal basis for the re-use/further processing of personal data** for developing certain AI systems in the public interest in one or more of the following areas:

  I. The prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security, under the control and responsibility of the competent authorities. The processing shall be based on Member State or Union law;

  II. Public safety and public health, including disease prevention, control and treatment;

  III. A high level of protection and improvement of the quality of the environment;

- Subject to **additional safeguards** including:
  - Data processed should be necessary for fulfilling one or more of the AI requirements (which cannot be effectively achieved by synthetic and non-personal data)
  - Effective monitoring mechanisms to identify high risks to fundamental rights
  - Processing should not lead to measures or decisions affecting the data subjects
  - Specific storage, access, security and documentation requirements

Art. 6(4) GDPR compliant

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Extra slides

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Regulatory Sandboxes

Dr Paul Campbell, Head of Software and AI, Senior Clinical Advisor, MHRA

Medicines & Healthcare products Regulatory Agency

25th September 2023

European Commission

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Introduction and Background

March 2015

"…the Government, regulators, business and academia must work together closely and in innovative ways."

November 2015

Regulatory Sandbox (definition)

"…a 'safe space' in which businesses can test innovative products, services, business models and delivery mechanisms without immediately incurring all the normal regulatory consequences of engaging in the activity in question."

What are the features of a Regulatory Sandbox?

- A regulator-monitored testing area, or ‘Sandbox’, for innovators to experiment with virtual environments or real people
- They create collaborative partnerships between innovators, regulators (inc. Approved Bodies), government & academia
- They allow the exploration of real, or perceived regulatory **barriers**, required **safeguarding** mechanisms and consideration of current or future **legislative** positions
- Used as a mechanism to generate **data** and **evidence** to assess if a future real-world application is a **viable** proposition

Potential Regulatory Sandbox (RS) Process

1. Manufacturer applies to use RS

2. Regulator (+/- relevant partners) review RS application

➤ NO – stop here OR ➤ YES – next step

3. Regulator & Manufacturer agree RS testing and monitoring approach

4. Regulator confirms approval to proceed. All related parties assist with deployment where able

5. Testing & Monitoring proceeds

6. Manufacturer creates a final report of product/project

➤ Regulator/AB provide written response to this report

7. Manufacturer then decides on next steps e.g.

➤ Apply to new AB, OR ➤ Amend product and repeat RS or follow standard AB process, OR
➤ Product disbanded, OR ➤ Manufacturer returns product to an initial research stage

Challenges and Rationale for RSs

1. Fit of new technologies to current regulatory systems can be challenging
2. Often, debate over the baseline level of evidence /regulatory knowledge in the innovation space
3. Addresses the ‘Barrier vs Team-Sport’ mindset
4. Whole/Total Product Lifecycle (TPLC) considerations are not appreciated
5. Poor understanding of feedback benefits & mechanisms required to support TPLC

The Benefits of Regulatory Sandboxes

Innovators

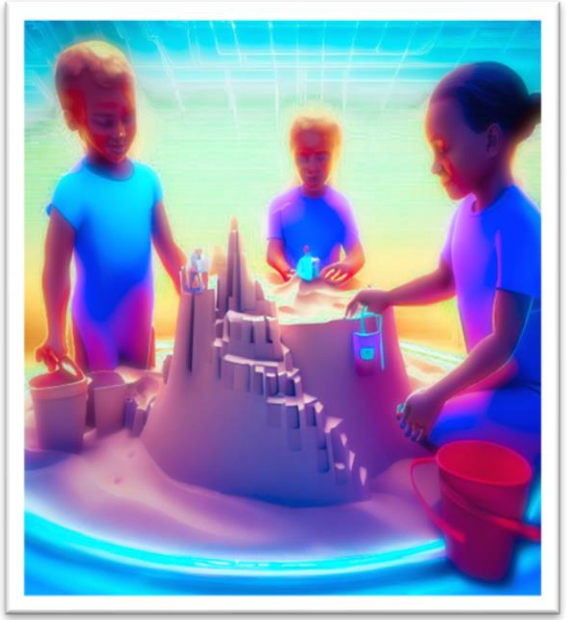
- Provides a supported environment to safely try new technologies
- Provides guidance on good approaches to evidence
- Provides insight into regulatory requirements

Regulators

- Structured mechanisms – for systematic testing and analysis, enhancing feedback loops
- Develop expertise for new technologies that may not quite fit
- Promotes collaboration
- Informs Regulatory policy

Patients

- Provides earlier access to innovative technologies
- Provides better evidence/assurance of safety and effectiveness of products
- Facilitates scalable product solutions for health care systems and patients



RS Summary

- Regulatory Sandboxes are a valuable part of the toolbox
- In healthcare, they should have a different, less play-time-like, more reassuring name!
- Sharing of experiences could help finesse the right model for ‘Regulatory Sandboxes
- They can foster collaborative learning internationally which can lead to accelerated alignment

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Regulatory Sandboxes

Koen Cobbaert - Philips

September 25, 2023

European Commission

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Regulatory Sandboxes used in three meanings

1 **Framework for negotiated rulemaking**
Framework set up for experimenting with technologies in view of developing new and updating existing legislation, implementing or delegated acts, guidance, standards, and administrative provisions.

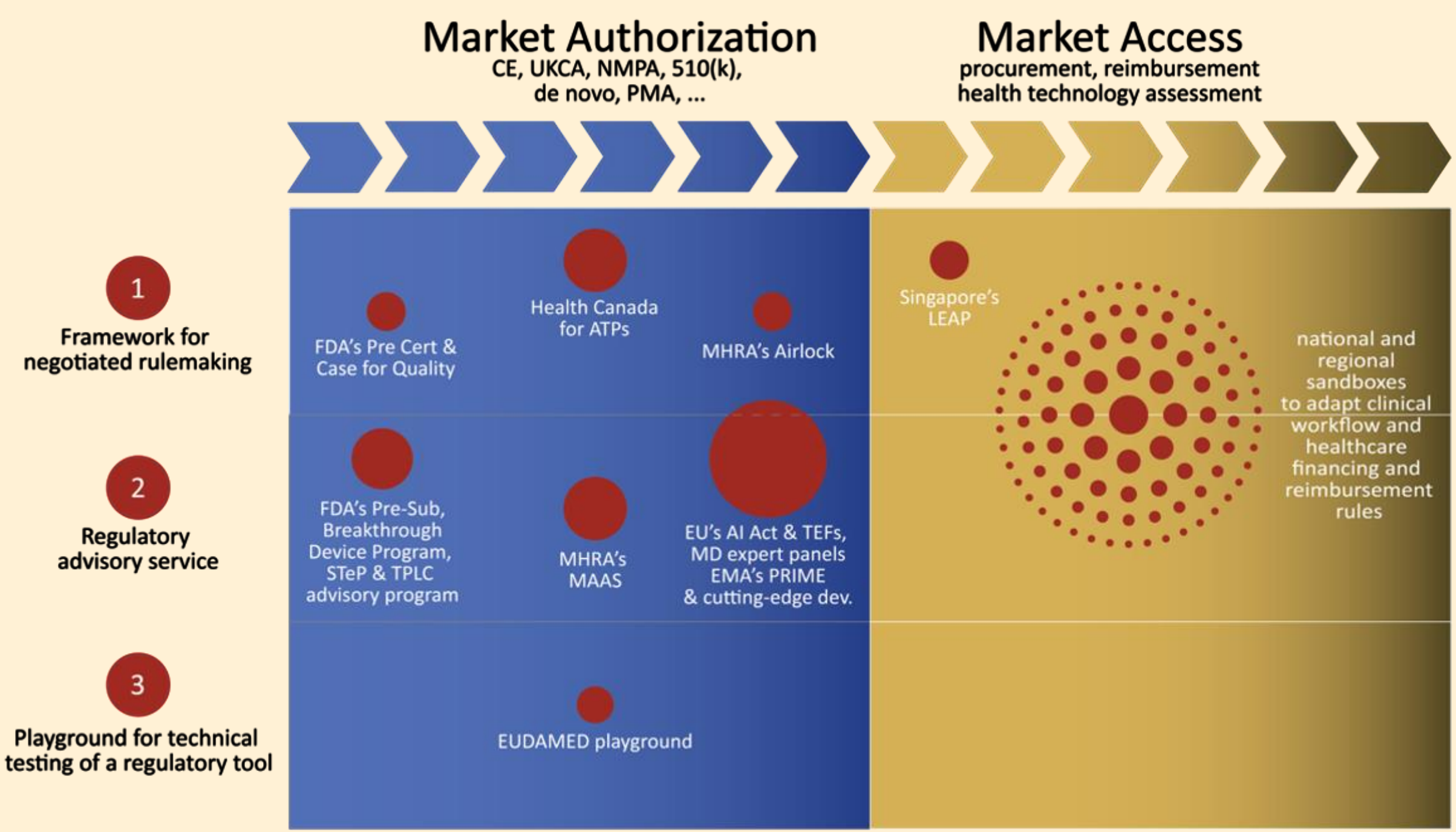
E.g., FDA's Pre-certification program, MHRA's Airlock, Singapore's LEAP for telemedicine

2 **Regulatory advisory service**
Advisory service providing scientific, regulatory, legal, and ethical advice on market authorization and/or market access of products and services. It may include a testbed to experiment with technology and gain insight into the extent of regulatory compliance.

E.g., MHRA's one-stop-shop for AI developers and users, EU's proposed AI Act regulatory sandboxes

3 **Playground for technical testing of a regulatory tool**
An application testing environment that isolates untested code changes and experimentation from the production environment.

E.g., EUDAMED playground


Market Authorization
CE, UKCA, NMPA, 510(k),
de novo, PMA, ...
Market Access
procurement, reimbursement
health technology assessment
1
Framework for negotiated rulemaking
2
Regulatory advisory service
3
Playground for technical testing of a regulatory tool
FDA's Pre Cert & Case for Quality
Health Canada for ATPs
MHRA's Airlock
Singapore's LEAP
national and regional sandboxes to adapt clinical workflow and healthcare financing and reimbursement rules
FDA's Pre-Sub, Breakthrough Device Program, STeP & TPLC advisory program
MHRA's MAAS
EU's AI Act & TEFs, MD expert panels EMA's PRIME & cutting-edge dev.
EUDAMED playground

Goals

1

Framework for negotiated rulemaking

Market Authorization

CE, UKCA, NMPA, 510(k), de novo, PMA, ...

Market Access

procurement, reimbursement health technology assessment

Allow legislators to

1. increase their understanding of the technology, the business models, risks, and incentives
2. determine whether existing legislation is fit for purpose, inform legislative initiatives (drafting or reviewing legislation) and enhance the regulatory system in view of better health outcomes, improved patient experience, improved user experience, lower cost of care, and helping people to take better care of their health at every stage of life
3. Issue opinions and recommendations for the drafting of legislative guidance, international standards, technical specifications and identify standards for potential harmonization or recognition
4. avoid overengineering/overfitting legislation to one specific technology

Allow health institutions, insurers, and manufacturers to

1. experiment with the new technology and its role in clinical practice
2. adapt the technology (safer/better utility/performance)
3. gain insight into clinical evidence
4. gain trust
5. reduce time to market/help patient

6. adapt the care processes, financing, and reimbursement rules
7. gain insight into clinical evidence or health economics

5. reduce time to market/help patient

Market Authorization
CE, UKCA, NMPA, 510(k),
de novo, PMA, ...

Market Access
procurement, reimbursement
health technology assessment

Desired Operating Parameters

1

Framework for negotiated rulemaking

- be voluntary
- be limited in time and space to avoid a two-tiered regulatory system
- provide harmonized/standardized eligibility criteria to avoid regulatory arbitrage and forum shopping
- encourage participation by
  1. providing a waiver from specific legal provisions or compliance processes or find other means to avoid inadvertently increasing the regulatory burden or financially penalizing the participants
  2. providing incentives, such as access to qualitative data for training, tuning, and testing purposes, supervisory discretion from traditional market authorization and/or market access processes, reduced fees, etcetera
- start with a commitment (e.g., letter of intent) in which all stakeholders engage equally and involve predetermined proof points
- appropriately staffed (they are resource intensive) with sustainable funding

- ensure conformity assessments are accepted by notified bodies, e.g., by translating technical aspects into harmonized standards or guidances

- target scalability across healthcare and economic sustainability for all stakeholders by avoiding costly bespoke customization and solutions

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Regulatory toolboxes to foster innovation

Dr. Bettina Möbius – Drägerwerk AG & Co. KGaA

25. September 2023

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Regulatory sandbox between regulatory and clinical affairs

Agenda


Regulatory
New Technology
Clinical
Photo: brombastic on Pixabay

Current approach

New technology must offer a clinical benefit to get regulatory approval

- A clinical benefit is defined as the positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome…. (EU 2017/745)
- similar device in clinical evaluation → human vs. technology

→ Contradictory example: device interoperability

Say goodbye to traditional thinking

European AI Act Proposal

- demands member states to provide regulatory sandboxes

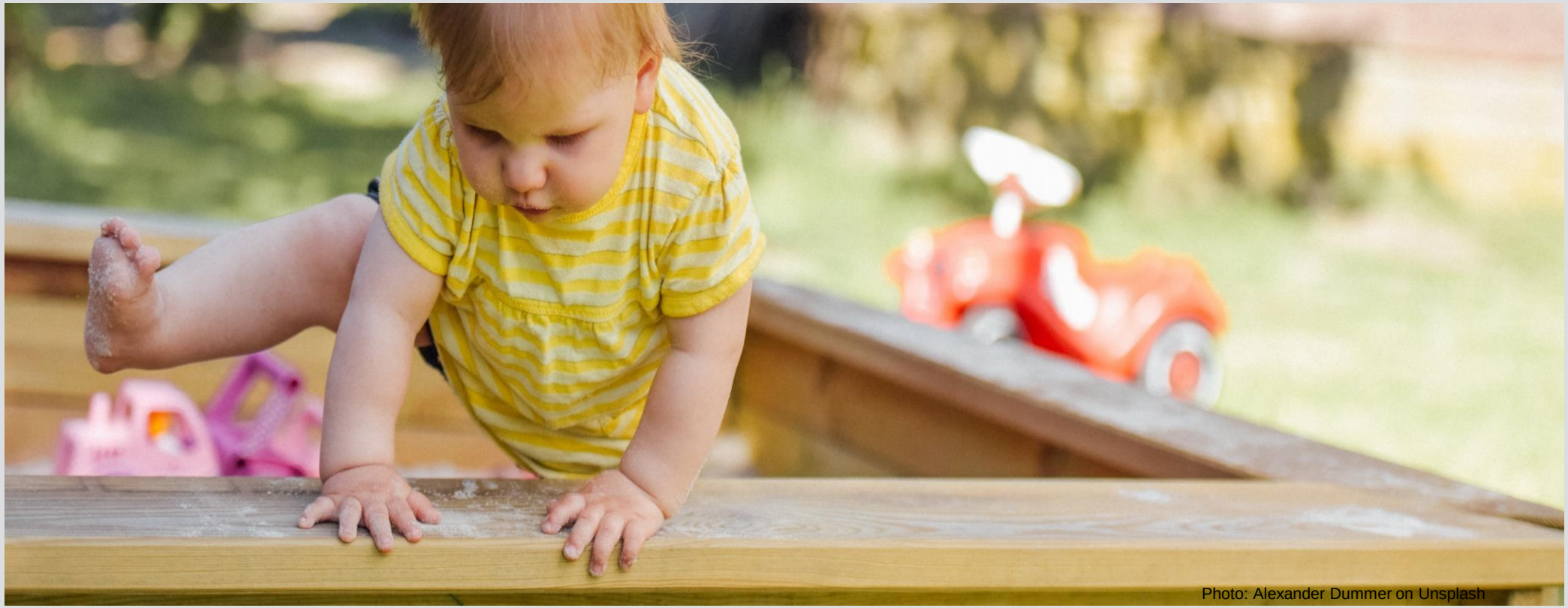

Photo: Alexander Dummer on Unsplash

Playing in the sandbox prepares for real life.

Quote: November 2020 “Digital Health 2020 - EU on the Move“

“We are partners with the developers and work together with you to improve the care of the patients with the new technologies enabled.“

European Commission and the German EU Presidency

Making space for innovation by regulators

- Provide MDR AI regulatory sandboxes for market surveillance and conformity assessment
- Make use of the new legislative framework to adapt MDR to foster innovative medical technology
- IMDRF WG AI regulatory sandboxes → should be an internationally harmonized accelerator for innovative medical technology

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Innovative tools in the regulatory toolbox

Yuan Peng, NMPA

25 September 2023

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The innovative development of the medical device industry has become a global concern topics. How to promote product innovation and ensure that medical devices applying new technologies and methods enter the market as soon as possible are the top concerns of every regulatory authorities.

For NMPA, recent years, we have also been supporting and encouraging innovation in the medical device industry from a policy perspective. For innovative medical devices, we will accelerate the approval process to ensure that they enter the market as soon as possible

The provision on Registration and Filing of Medical Devices (SAMR decree No.46)

Chapter 4 of the provision point out three kinds of special registration procedures

- Innovative Product Registration Procedure (Section 1)
- Priority Registration Procedure (Section 2)
- Emergency Registration Procedure (Section 3)

Clearly define the scope, procedures, and support policies for each procedure.

Innovative Product Registration Procedure

The Scope:

In China, **own the core technology invention patent rights** of the medical device legally;
and the products are **basically standardized**;
and the main principle or mechanism is the **domestic initiative in China**, and the performance or safety of the products have been fundamentally improved compared to similar products.
The technology is **at the international leading level** and has **significant clinical value**.

The Acceleration Methods:

- The CMDE(Center for Medical Device Evaluation, belong to the NMPA) will designate a special person, who is the reviewer of the CMDE, and responsible for communication,
- and the CMDE will guide the manufacturer to prepare the registration application documents and materials during the whole registration process, and for example: the clinical evaluation materials, the non-clinical evaluation materials;
- and the test center will test priority, the Local MPA will carry out the QMS inspection priority, the CMDE will evaluate priority, the NMPA will approve priority.

till now, the NMPA had approved 230 innovative medical device, for example: 56 AI medical device, ion therapy system, Surgical robots, 5.0T MRI and so on

Priority Registration Procedure

The Scope:

two principles:

- urgent need for clinical use
- with significant clinical advantages

- 1. Diagnose or treat rare diseases ;
- 2. Diagnose or treat malignant tumors;
- 3. Diagnose or treat specific and multiple diseases of the elderly;
- 4. Specially designed for children;
- 5. There is an urgent need for clinical use, and no same variety medical devices approved in China.

The Acceleration Methods:

- The CMDE (Center for Medical Device Evaluation, belong to the NMPA) will evaluate priority, the NMPA will approve priority.
- and the manufacturer should submit the application for priority registration procedure with the medical device registration application, and the CMDE will organize experts for discussion in order to draw a conclusion, if the medical device can be included in the priority procedure.
- The CMDE will strengthen communication with manufacturer(compare with the innovative medical device, the CMDE don’t designate the special person)

Guidance for medical devices conditional approval

For medical devices **that seriously endanger life and do not have effective treatment methods for diseases**,

The NMPA will consider the balance between the expected data collected post market and collected pre-market, and a comprehensive evaluation of the product's risk and benefits should be conducted.

The data collected pre-market should prove that the medical device has shown effective and can reasonably predict the clinical value, and the medical device can be approved with conditions.

Regulatory scientific research, support for medical devices innovation

As we known, regulatory science research is a work that different regulatory authorities are committed to carrying out.

In April 2019, the China Drug Regulatory Science Action Plan was launched; The second batch of key projects will be implemented in June 2021.

The plan’s purpose: focusing on the theme of "innovation, quality, efficiency, system, and capability", promote innovation in regulatory concepts, systems, and mechanisms, and accelerate the pharmaceutical industry

The NMPA hope to discover more tools, methods, and standards through the regulatory scientific research program, further improve the supervision of products adopting new technologies, improve regulatory requirements, and better promote industrial innovation and development

The NMPA had established 9 regulatory scientific research bases.

Below are some projects (for medical devices):

- Real world data supports research on evaluation methods for innovation medical devices, and urgent need for clinical use medical device
- Research on the evaluation of diagnosis products for new emergent Infectious diseases
- Research on the safety, effectiveness, and quality control evaluation of nano innovative medical devices
- Research on the evaluation of Innovative medical devices based on remote transmission, flexible electronic technology, and medical robots
- Research on the safety and effectiveness evaluation of new biomaterials
- Research on new tools, standards, and methods for evaluating diagnostic and treatment products for common and frequently occurring diseases such as malignant tumors

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Predetermined Change Control Plans (PCCPs)

Dr Russell Pearson, AI Regulatory and Policy Lead, MHRA

Medicines & Healthcare products Regulatory Agency

25th September 2023

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Introduction and Challenges of change management

Products can need updating (especially in the software space)

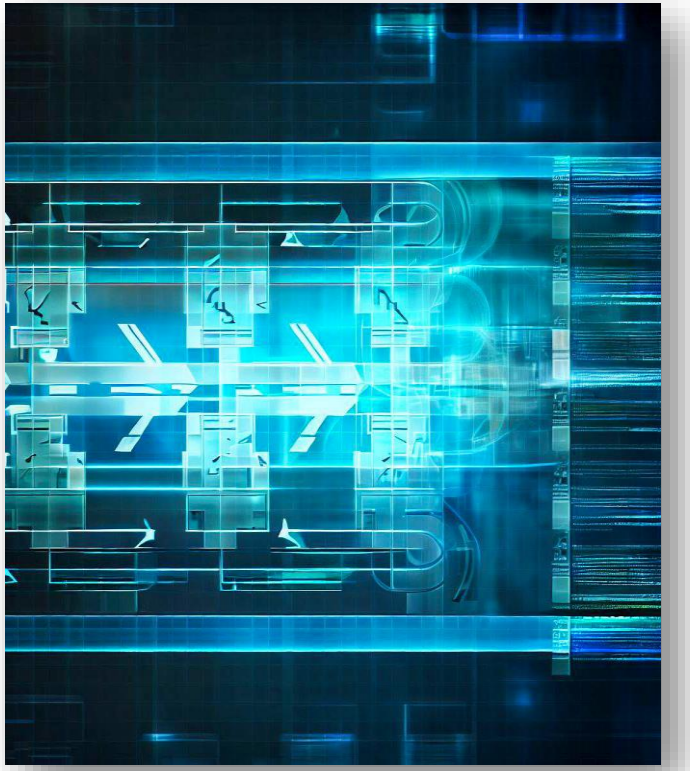
For many jurisdictions, changes require some form of resubmission and assessment

Some products may need to update frequently for safety reasons

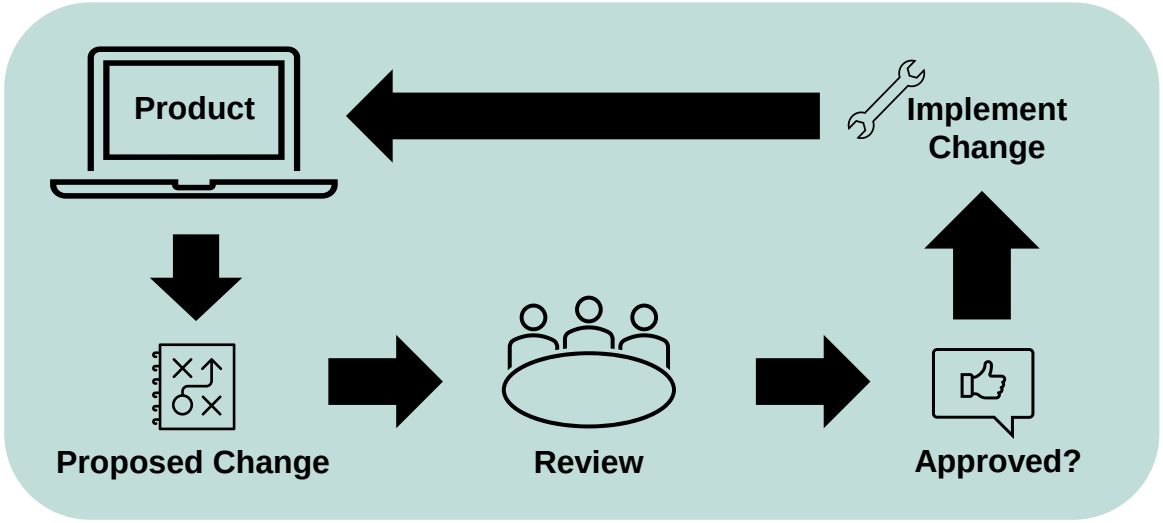
For products that change frequently, this can become administratively burdensome for both regulators and manufacturers

What are PCCPs ?

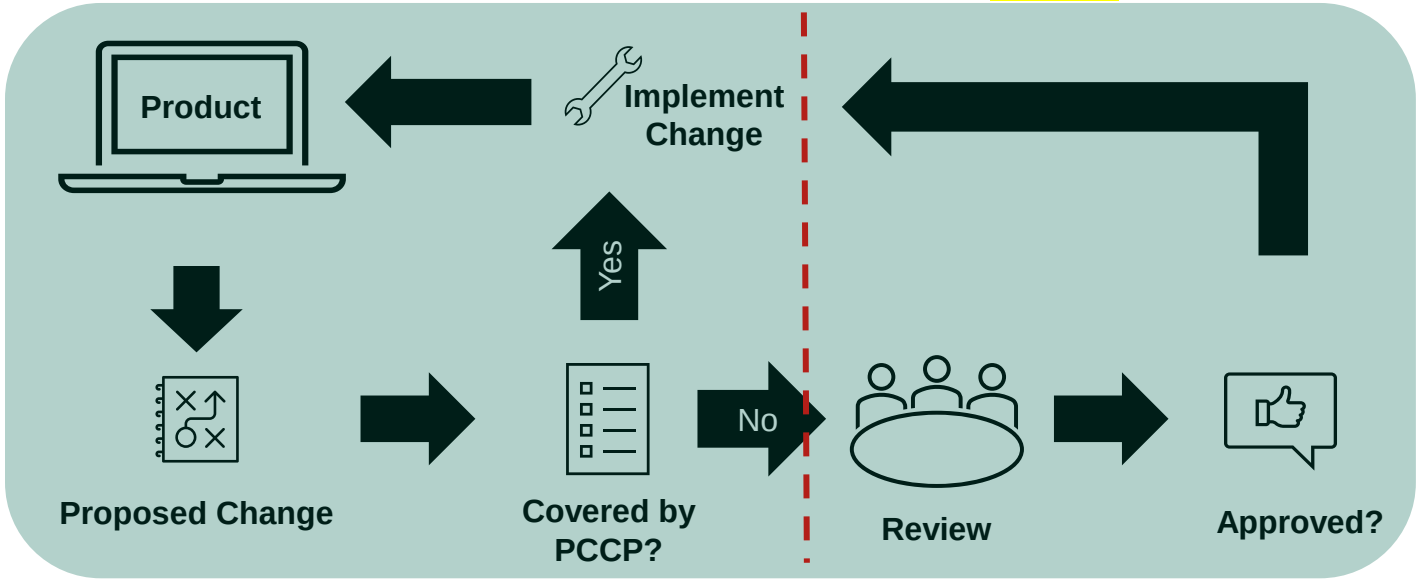
- Software and AIaMD products typically need to change more frequently than traditional hardware products.
- Predetermined Change Control Plans (PCCP) are a new regulatory process designed to address this wider change management workload issue, mostly for software and AI products.
- The concept is to allow specific change events and how to manage them to be identified ahead of time. These are documented, validated and assessed akin to a product component with the details held in the technical documentation.
- This is a global issue impacting different regulatory jurisdictions in a similar way.



Product Change Management without PCCPs



Product Change Management with PCCPs



Potential Risk / Issues around PCCPs

1. Poor evidencing/trying to set up a PCCP too soon in the TPLC

2. Implementation issues/slotting in with existing quality and regulatory processes

3. Product creep/straying outside the intended use

The Benefits of a Well-Functioning PCCP

Manufacturers

- Resource savings over time
- Improved product safety and compliance
- Enables continuous improvement activities

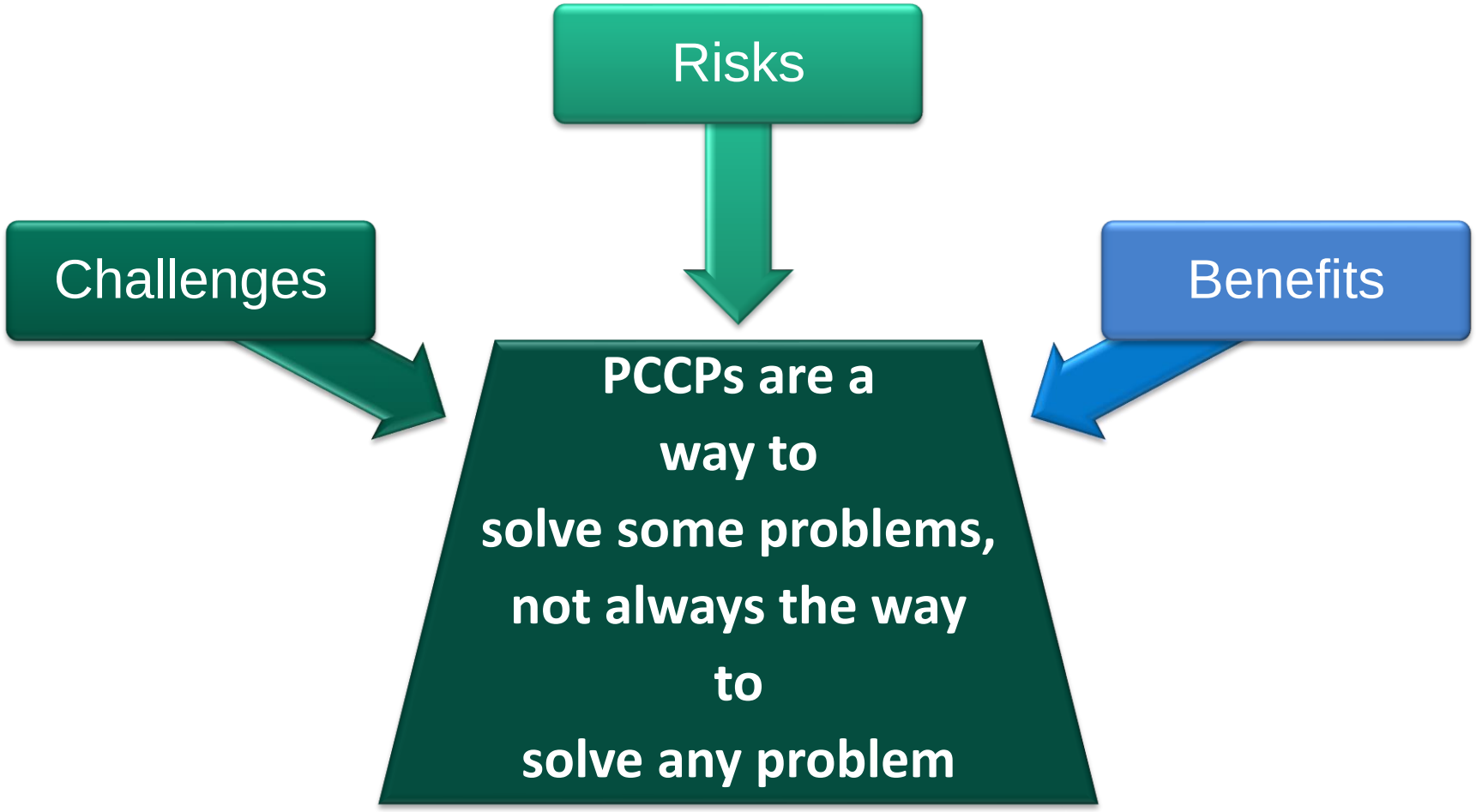
Regulators

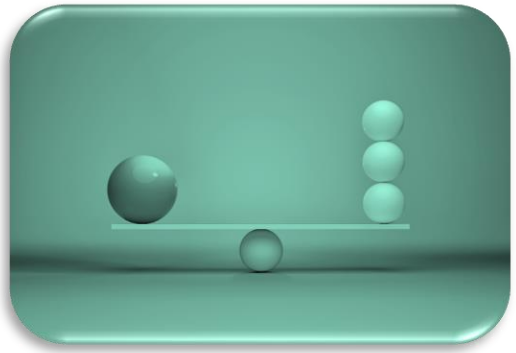
- Resource savings/repurposing to more safety critical activities
- Safer products and greater safety signal
- Additional documentation to understand products

Patients

- Greater confidence in stable performance in products generally
- Faster resolution of safety concerns
- Improved person-centred care possibilities

PCCPs Summary





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Predetermined Change Control Plans Supporting Efficient Regulatory Oversight

Cassie Scherer, Medtronic for GMTA

25 September 2023

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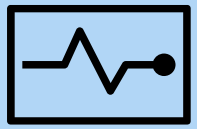
Digital health in medicine

Offering potentially revolutionary capabilities

The use of digital health, including AI-enabled medical devices, has the potential to address some of the most critical challenges in healthcare

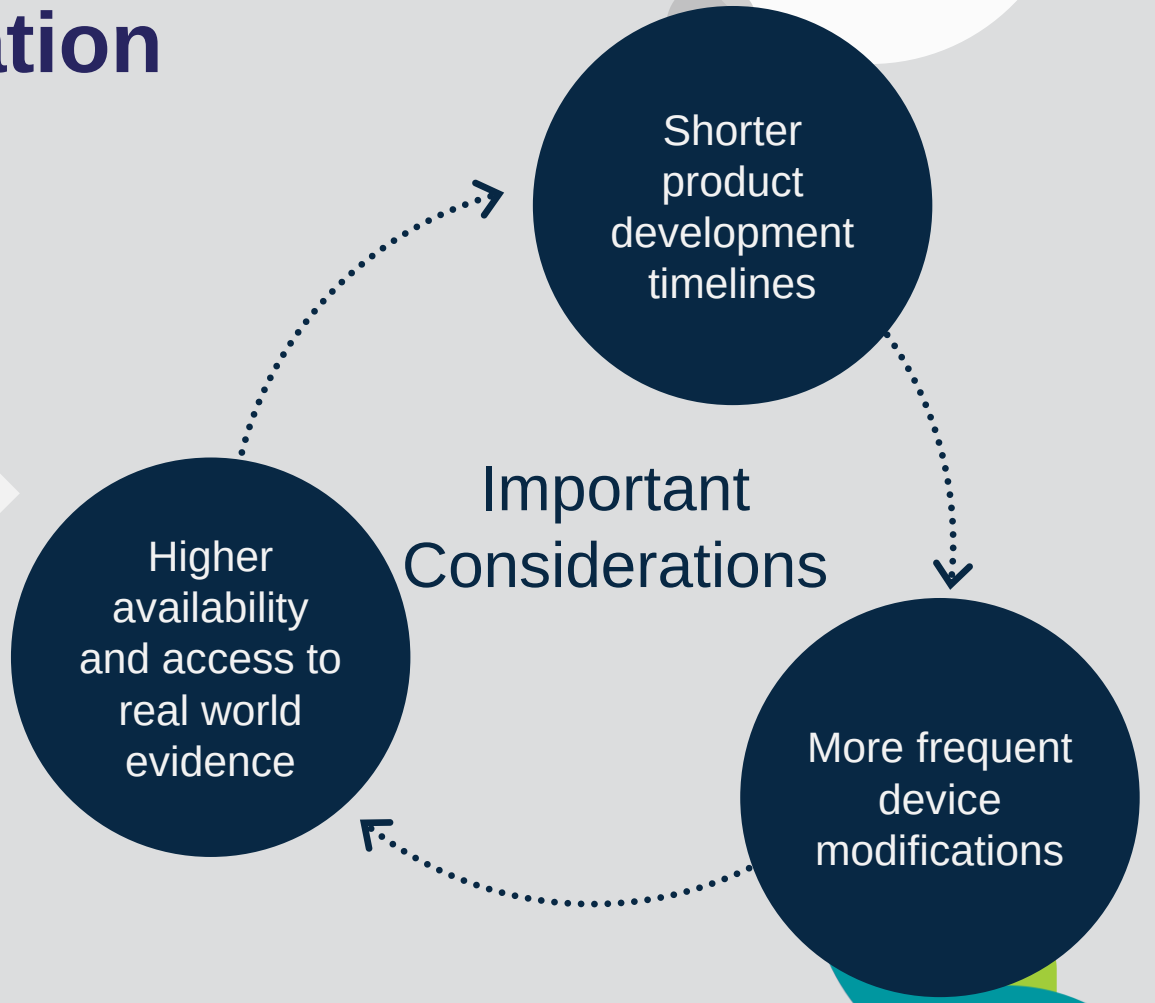
With dramatic increase in connected devices and electronic health record data, there is both increased opportunity to understand and treat patients, as well as increased burden on physicians



Digital health solutions, if leveraged responsibly, offer the opportunity to provide meaningful insight driven care

Laying the groundwork for efficient & harmonized digital health regulation

Traditional paradigm of medical device regulation was not designed for rapidly changing digital health technologies

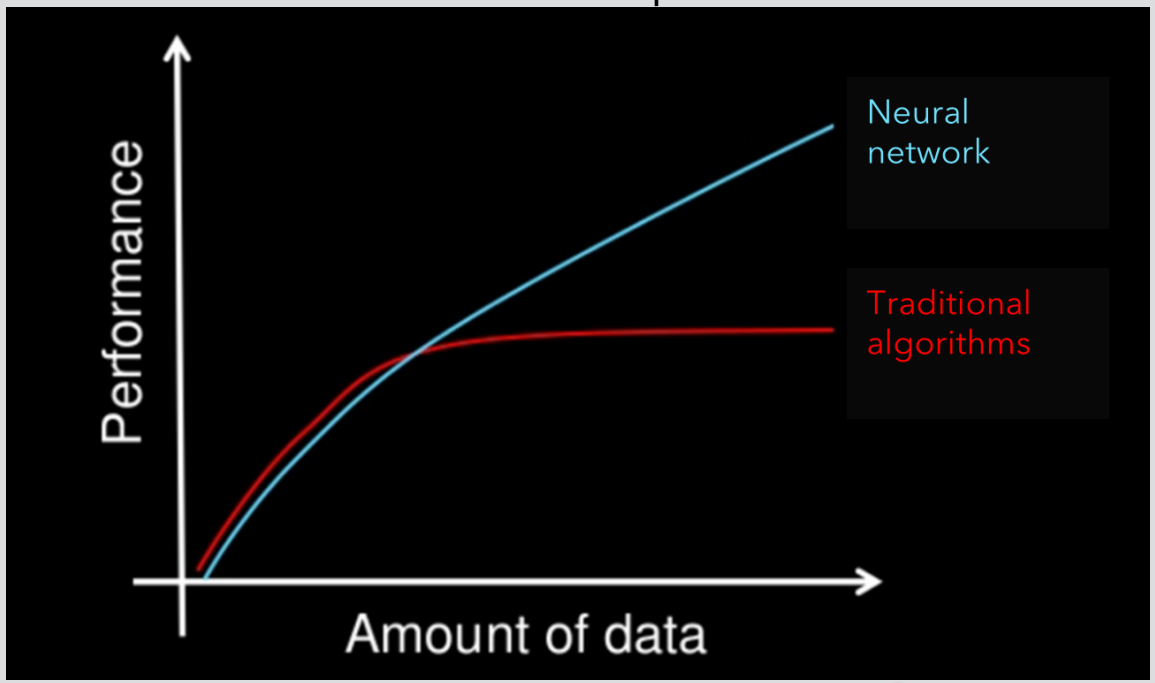


Importance of PCCP: Example

Neural network/AI uniquely suited for more rapid iteration

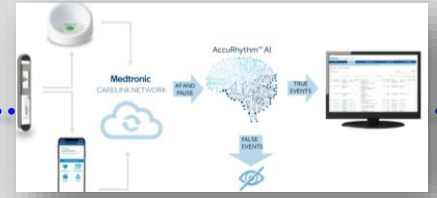
- Evolution of AI-enabled products can be quite rapid, in tension with typical regulatory process used for other medical devices
  - Compared to traditional algorithm development, AI techniques (particularly neural networks) allow for continued notable improvement with increased training data

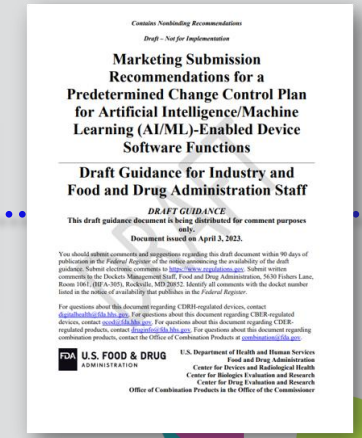
Neural network/AI continues to improve with more data



U.S. experience: Expanding use of PCCPs across all products

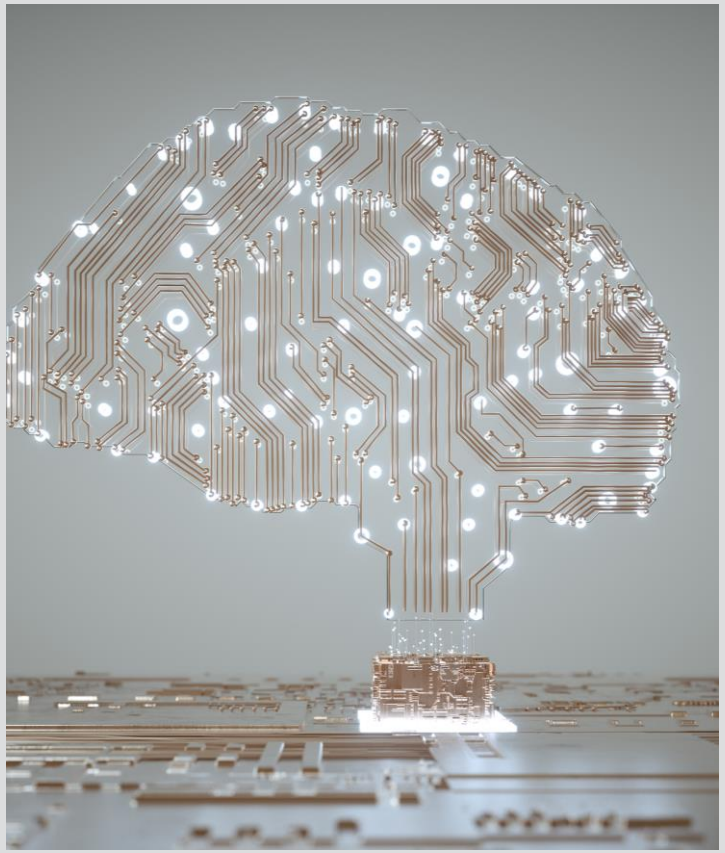
April 2019	January 2021	June 2021	December 2022	April 2023
FDA AI/ML-based SaMD discussion paper introduces PCCP concept	FDA AI/ML-based SaMD Action Plan commits to draft guidance	Several products received FDA authorization for PCCP from 2020-2022	**Legislation expands voluntary use of PCCP across all premarket pathways and with *all* devices**	FDA releases AI/ML PCCP draft guidance




Contains Nonbinding Recommendations
Draft – Not for Implementation
Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions
Draft Guidance for Industry and Food and Drug Administration Staff
DRAFT GUIDANCE
This draft guidance document is being distributed for comment purposes only.
Document issued on April 3, 2023.
U.S. FOOD & DRUG ADMINISTRATION
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research
Center for Drug Evaluation and Research
Office of Combination Products in the Office of the Commissioner

! PCCP no longer limited to AI/ML-enabled devices

PCCP benefits & considerations



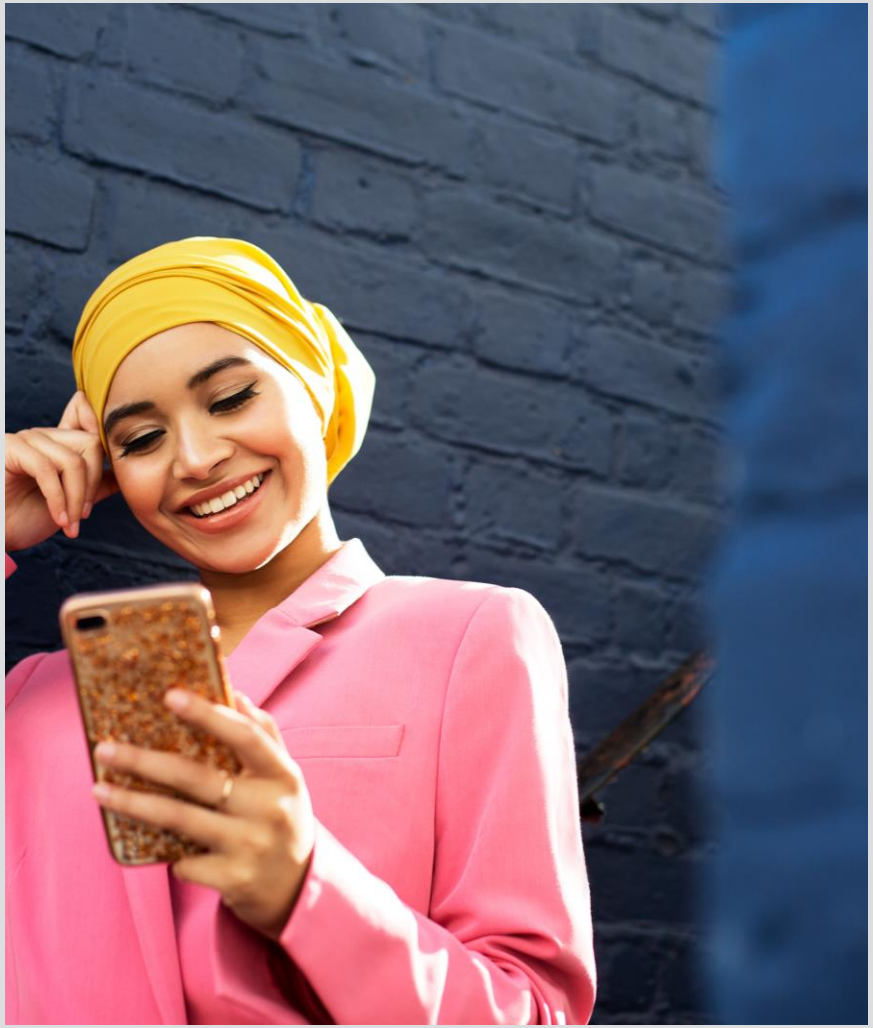
Allows manufacturer to make specific modifications postmarket without new marketing authorization --- furthering more rapid positive product evolution & improvements for patient care

Reduces burden for regulators by reducing total number of reviews for a product

Modifications included in PCCP should be those that would otherwise require premarket review. Can be utilized for modifications implemented manually or automatically

Goal is a regulatory approach that strikes a balance of sufficient premarket confidence and postmarket efficiency

Commitment to transparency



PCCP includes a plan to address how changes will be communicated to users

Communication is provided to notify users when new version has been deployed

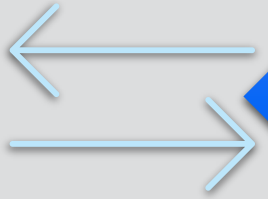
- For example, content includes description of changes, impact on performance, and reference to updated manual

Electronic instructions for use (eIFU) helps facilitate rapid notification to users

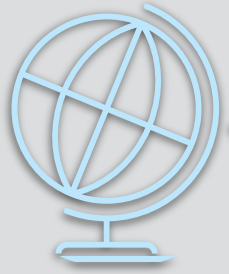
- Benefits of eIFU also include environmental benefits and increased availability, utility, interactivity, and accessibility to labeling

PCCP: Key take-aways

Beneficial to allow for **further optimization of the technology** without new marketing authorization while still ensuring safety and effectiveness



Important for changes that would **otherwise need premarket review**



Harmonization of PCCPs is key to encouraging innovation globally

THANK YOU / QUESTIONS

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European Commission

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Fostering Innovation Predetermined Change Control Plan

April Veoukas, Abbott for GMTA

25 September 2023

European Commission

Funded by the European Union

Medical Device Development

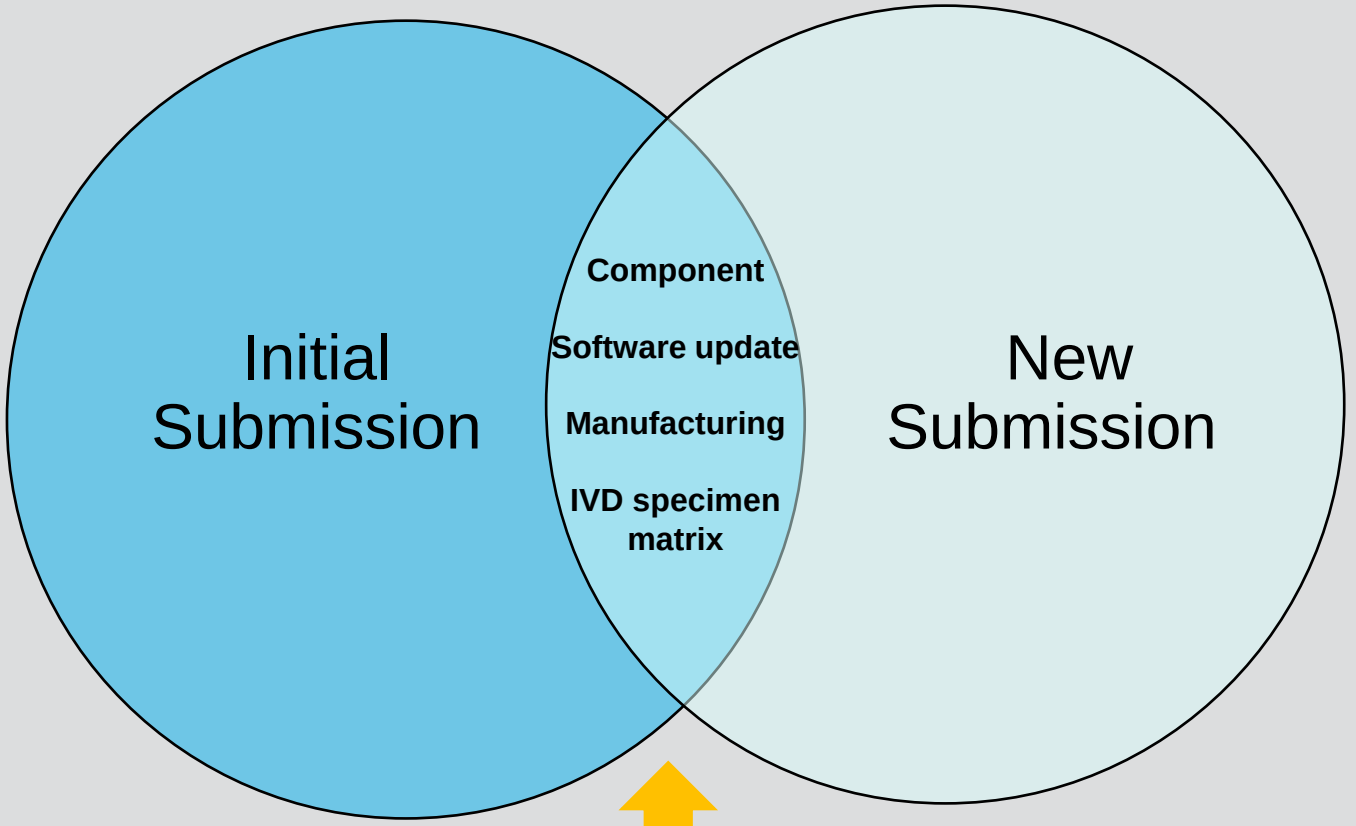
ITERATIVE advancements supported by

AGILE processes foster

INNOVATION and benefit

PATIENTS

CHANGES ELIGIBLE FOR PREDETERMINED CHANGE CONTROL PLAN (PCCP)



Subset of changes requiring notification and approval before implementation become eligible for PCCP.

AGILE CHANGE MANAGEMENT

Without PCCP

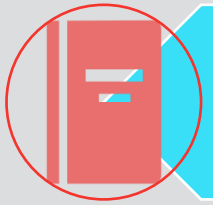
- Premarket submission/Approval
- Device to patient
- Test/validate change
  - Document in QS
- Premarket submission
- Review
- Approval
- Enhanced device to patient

With PCCP

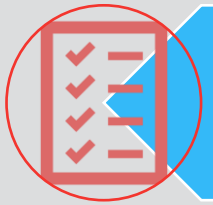
- Premarket submission/Approval
  - Change control plan
- Device to patient
- Test/validate change per PCCP
  - Document in QS
- Enhanced device to patient

COMPONETS OF A PCCP

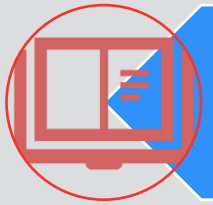
Description of Change



Validation Protocol



Acceptance Criteria



Labeling (if applicable)

Predetermined Change Control Plan (PCCP)

ITERATIVE advancements supported by AGILE processes foster GLOBAL INNOVATION and benefit PATIENTS GLOBALLY

THANK YOU / QUESTIONS

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Innovative tools in the regulatory toolbox

Anna Hallersten, Roche Diagnostics for GMTA

25 September 2023

European Commission

Funded by the European Union

Diagnostics (IVDs)

- **Screening**: am I at risk?
- **Prevention**: what can I do to prevent falling ill?
- **Early detection**: am I ill?

- **Diagnosis**: what is wrong with me?
- **Stratification**: what are the details?
- **Treatment**: what treatment is best for me?

- **Prognosis**: will I get better?
- **Therapy monitoring**: is it working?
- **Disease management**: can I live a normal life?

- IVDs influence ca ⅔ of all clinical decision-making
- …but only **2%** of total healthcare spending*

To reach healthcare systems without delay, IVDs need regulatory oversight** that is

➔ Risk-based
➔ Globally convergent
➔ Nimble
➔ Efficient
➔ Connected

*The value of in vitro diagnostic testing in medical practice: a status report. PLoS One 2016;11:e0149856 link.

**Principles of ideal diagnostic regulation and the IVDR, CCLM, Volume 61 Issue 4 link

The regulatory toolbox for diagnostics (IVDs)

SCOPE

Qualification
Classification
RUO/LDT
Nomenclature
Borderline

PATHS

Premarket approvals
Premarket notifications
Self-declaration
Compassionate use
Emergency use

EVIDENCE

Data generation
Study requirements
RWD/RWE
Overseas data
Life-cycle approach

LABELING

Label
Labeling/IFU
Digitization
User requirements

SUPPLY CHAIN

Manufacturing
Importer/exporter
Traceability & UDI
Distributors
Warehousing

SAFETY

PMS
Incident reporting
Trend reporting
Inspections

GOVERNANCE

Oversight
Decision-making
Appeal
Fees
International issues

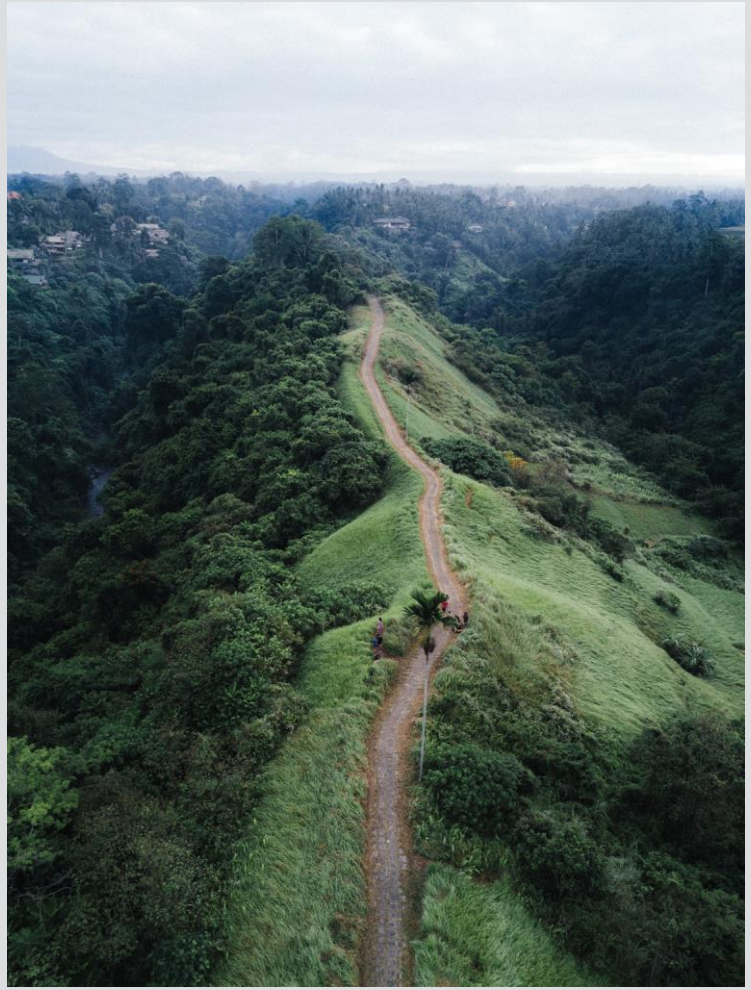
INFRASTRUCTURE

Expertise, capability
Processes, databases
Guidance mechanisms
Digitalization
Regulators' QMS

CONNECTIVITY

Interoperability
Interfaces (AI, environmental, pharma)
Data processing

Innovative paths in the regulatory toolbox



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PCCPs & pre-cert's
Orphan use
Sandboxes/airlocks

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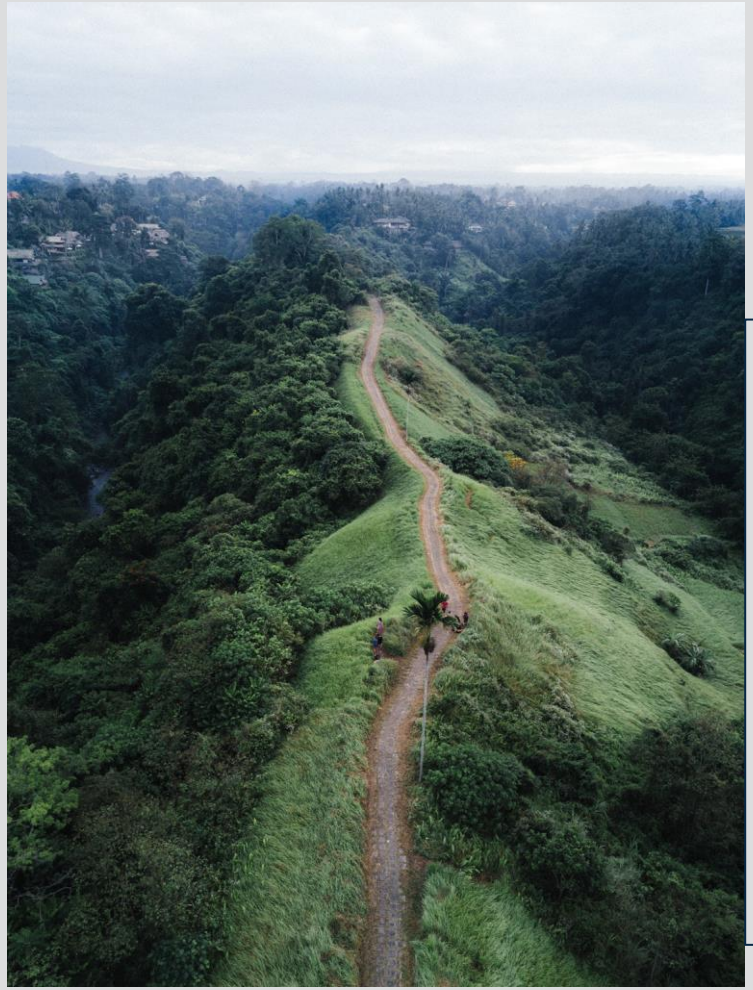
Ideas for refinement of *innovative* paths



PATHS
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- Expand **pre-cert** models to e.g. well-established products (typically long experience/low risk)
- Explore **pre-cert** models for use in public health emergencies to remain nimble
- Develop system/process/entity-based **KPIs** for use in PCCP models and pre-cert models

- Foresee where use of innovative tools impact other requirements, e.g. labelling
- Think early about needed infrastructure for new regulatory models e.g. IT **interfaces**
- Foster **convergence** for global mind-set on e.g. changes to support reliance

- **Share globally the learnings** from pilots on new tools
- Involve industry and other stakeholders in **ideation**
- Apply a **principle-based** approach to the design of new tools and models

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THANK YOU / QUESTIONS

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