12–15 SEPTEMBER | VIRTUAL CONFERENCE

TOGETHER FOR PATIENTS

Transforming the Regulatory ecosystem in Africa

DAY 3 | How can Africa pioneer regulatory system innovation and digitalization?

2023 AFRICA REGULATORY CONFERENCE

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THANK YOU FOR JOINING!
Participant guide

- The 5th AfRC conference is held in English.
- All participants are muted. We encourage you to use the Q&A box to raise questions to the speakers. If a question you would like to ask has already been raised, you can also "like" that question.
- For some sessions, participants will have the opportunity to also engage with speakers through Mentimeter polls. To take part, a QR code will be displayed on screen and a link will be shared in the chat box.
- We encourage you to join all conference days.
- The 5th AfRC conference is recorded. All speaker presentations and videos will be made available on the africaregulatoryconference.ifpma.org website after the conference.

Présentations en anglais. Veuillez appuyer sur le globe pour avoir l'interprétation en français.
Apresentações em inglês. Clique no globo para interpretação em português.

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AfRC Track 05

Regulatory Digitalisation – New trends for a modern Agency

Session Moderator:

Teresa Eastwood-Kiefer

Chapter Leader, Regulatory Data and Content F. Hoffmann-La Roche

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Welcome!

We have the opportunity for Africa to leapfrog other regions and become **one of the most efficient and modern regulatory systems in the world.** This opportunity can rapidly transform into reality, by using the experience gained from a decade of harmonization activities in the continent, learnings gained during the pandemic and the swift implementation of modern and innovative solutions

What will it take?

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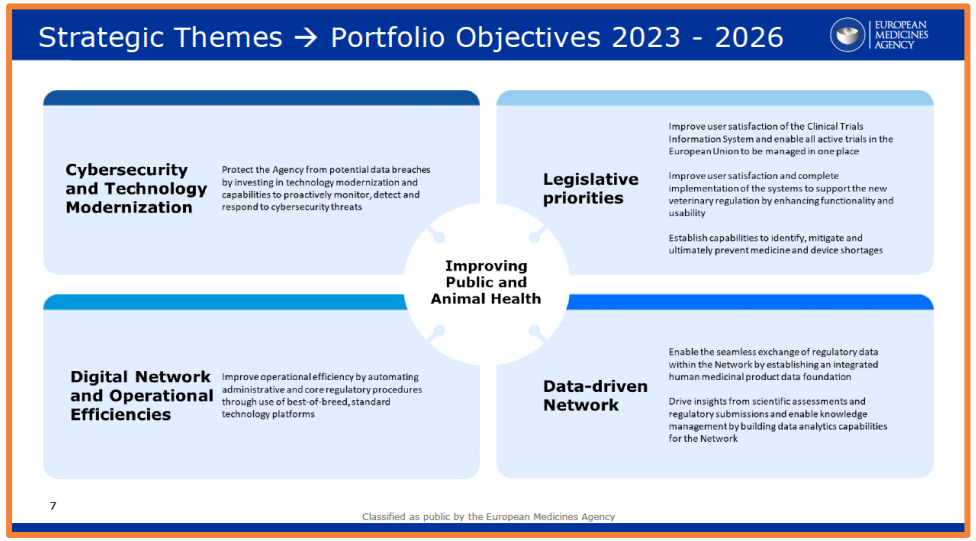
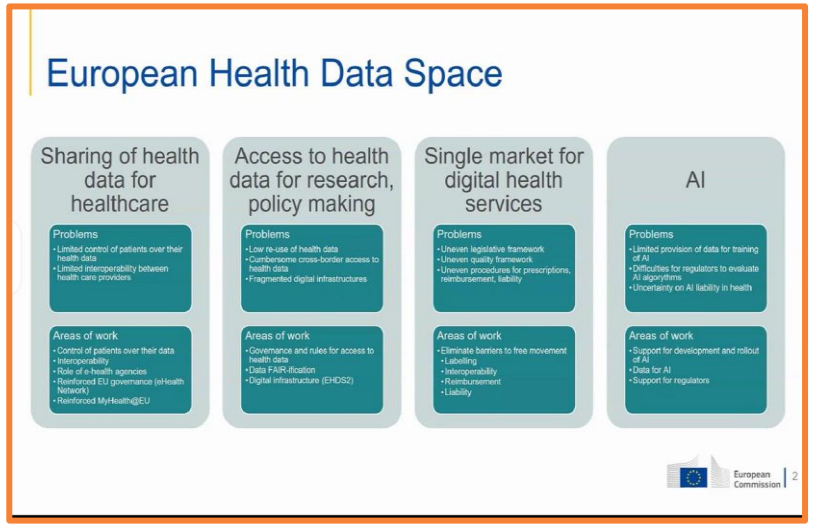
Digital and data transformation initiatives





New data types require new systems and tools

Report Name	Date Published
ODT Strategic Plan, 2023 - 2025	December 2022
ODT Annual Report 2022	December 2022
FDA Leadership Modernization Action Plan	December 2022
Cybersecurity Modernization Action Plan	November 2022
ODT Diversity, Equity, Inclusion, and Accessibility Action Plan 2023	November 2022
Enterprise Modernization Action Plan	May 2022
Modernization in Action 2022	March 2022
Data Modernization Action Plan	March 2021
FDA's Technology Modernization Action Plan	September 2019

Source: https://www.fda.gov/about-fda/office-digital-transformation/odt-reports

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Shifting the paradigm: Data-Driven Regulatory

Transforming Sponsor/Regulator collaboration with structured data submissions in the cloud

- e-paper (PDF)
- Static data shared at pre-defined stages
- Disparate data repositories
- Country by country submissions

- Harmonized structured data standards with global accessibilities
- Increased reliance approach and worksharing initiatives
- Rolling cloud-based data-submissions with dynamic regulatory assessments

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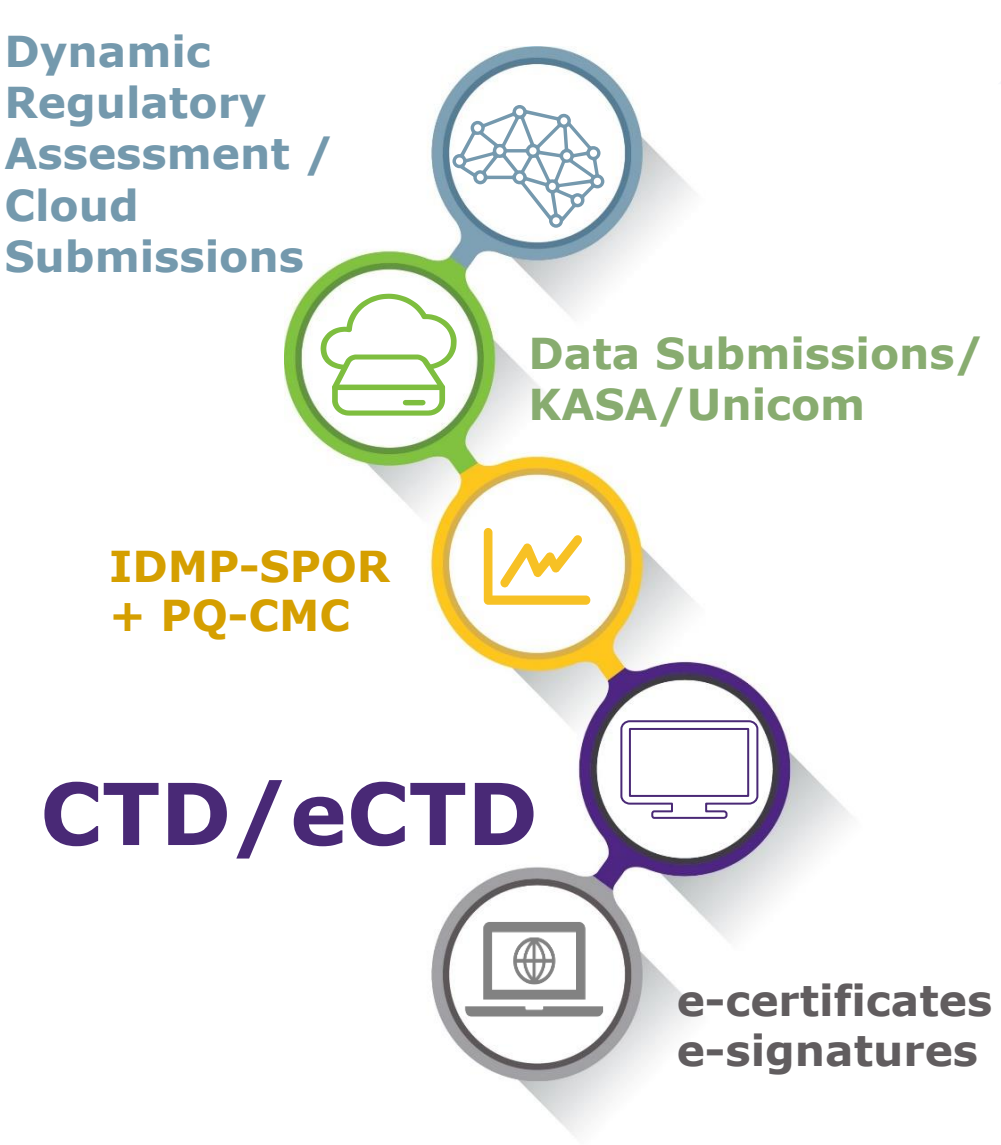
Stepwise approach to Digital Transformation



transformational

foundational

Transform for greater value and experience to patients:
- Dynamic Regulatory Assessment
- Cloud Submissions/Access/Accumulus Synergy
- AI-assisted data analytics to support decision making

Streamline processes
- Data submissions, Data Analytics Support, KASA, UNICOM
- Cloud-based storage
- Leveraging digital technologies, automation, to improve processes
- Connect and centralize siloed information

Structure information
- IDMP + SPOR + PQ-CMC
- Structured Product Quality Submissions
- Structured content management

Organize information
- Harmonize submission formats and standards to ICH
- CTD, eCTD

Digitize information: digitally enable e.g., e-certificates, e-signatures, e-consent forms, portals for exchange

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Presentation by:

Emmanuel Owusu Adasi

ICT Officer

FDA Ghana

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THE IMS TC

The IMS Technical Committee's purpose is to advise the AMRH Steering Committee on regulatory information management systems to be implemented at the National, regional and continental levels.

- To provide support and monitoring of the implementation of IMS activities.
- Advise on continual reviewing and updating of existing systems.

KRA 1: AMRH WEBSITE ENHANCEMENT

Key Result Areas	Activity	Expected output	Indicator	Target	Timelines 2023											
					Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec
Key Result Area 1:	**AMRH Website Enhancement**															
Activity 1.0	Content development and AMRH online platform management	Updated content on the website developed	Availabilty of timely content on the website	1	x			x			x			x		
Activity 1.1	Incude additional Technical Committees	Updated Website							x							
Activity 1.2	Include the Link to the FR Path									x						
Activity 1.3	Include a link to the RISP Portal													x		
Activity 1.4	Include Partnership reports from meeting and Partners Logos								x		x			x		
Activity 1.5	Core information to be published									x			x			x
Activity 1.6	M&E Dashboard to be developed									x						
Activity 1.7	Add Secretariate Contacts						x			x						x
Sub-total KRA 1					**Jan**	**Feb**	**Mar**	**Apr**	**May**	**June**	**July**	**Aug**	**Sept**	**Oct**	**Nov**	**Dec**

KRA 2: REGULATORY INFORMATION SHARING PORTAL

Sub-total KRA 1					Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec
Key Result Area 2:	**Regulatory Information Sharing Portal (RISP)**															
Activity 2.1	Document Management System Implementation	Collaboration and Information Sharing Platform for AMRH	Colaboration and information sharing platform	1					x	x	x	x	x	x	x	x
Activity 2.2	Gap analysis and User requirement specifications (Identifying the list of information to be shared)	Gap analysis conducted informastion sharing and URS developed in accordance with WHO ML3 Standards	Gap analysis Report and URS available	1								x				
Activity 2.2.1	Gap analysis on information sharing	Gap analysis conducted	Gap analysis report					x								
Activity 2.2.2	Identificastion of Information to be shared	Information to be shared	Report on information to be shared					x								
Activity 2.2.3	Stakeholders engagement (RISP)	Stakeholders engaged	Engagement Report					x			x					
Activity 2.2.4	Develop User Requirement Specification	User Requrements	User Requirement Specification Report					x								
Activity 2.3	Data Gathering	Data collected	Publication of Data on propotype RISP				x									
Activity 2.2.1	Using excel to get data from NMRAs						x									
Activity 2.2.2	Extracting Data from NMRA Websites						x									
Activity 2.2.3	Data Validation						x									

KRA 3: MODEL RIMS SOLUTION

Key Result Area 6	Model National RIMS Solution				Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec
Activity 6.1	Create Awareness on National RIMS Model						x	x	x	x	x	x	x	x	x	x
Activity 6.2	Develop User Requirements Specification														x	
Activity 6.3	Develop Technical Specifications Documents (Design and Fucntional Requirements)														x	
Activity 6.4	System Development															x
Activity 6.2	Systems Testing															x
Activity 6.3	Systems Validation															x
Activity 6.4	Piloting															x
Activity 6.5	Data Migration															x
Activity 6.6	Approval															x
Activity 6.7	Training															x
Activity 6.8	Go Live															x
Activity 6.9	Launch															x

KRA 4: DEPLOYMENT OF ECTD / E-SUBMISSION FOR CONTINENTAL DOSSIER MANAGEMENT

Sub-total KRA 4	**Technical committee on IMS operational**																				
Key Result Area 5 - Year 3 and 4 (2024 and 2025)	**Continental eCTD Solution**				**Jan**	**Feb**	**Mar**	**Apr**	**May**	**June**	**July**	**Aug**	**Sept**	**Oct**	**Nov**	**Dec**	**Jan**	**Feb**	**Mar**	**Apr**	**May**
Activity 5.1	Awareness for adoption	Adoption	Newsletter, Videos etc				x		x			x			x						
	Alignment with the Evaluation of Medicinal Products (EMP TC)		Meeting Reports and Workplans														x				
	Support Cross-REC learning using ECOWAS e-CTD model		Leasons Learnt Report																x		
	Constitution of a Project Team		Established Project Team																	x	
	Customisation of Continental e-CTD Specification	eCTD Specifications developed	Specifications 1.0																		x
	Industry Specification Workshop and Pilot Launch		Workshop Report																		x
	Authority and Industry training		Training Report																		x
	Final Specifications		Approved Specifications																		x
Activity 5.2	eCTD Software Setup and Customisa	eCTD Software Implemented	eCTD Software UAT Report																		x
Activity 5.2.1	Licensed Software		Software Licenses																		x
Activity 5.2.2	Configuration		Maintenance Report																		x
	User Training (Training on the Tool)		Training Report																		x
	Validation		Validation Reports																		x
Key Result Area 5	**Continental eCTD Solution**																				

ROADMAP / WORKPLAN

(SUMMARY)

- AMRH Website Enhancement - Achieved in Dec 2022 and upgrade is ongoing.
- Development of Regulatory Information Sharing Platform (RISP) - The Project is ongoing, and a consultant will be engaged before the end of September 2023.
- Development of Model Regulatory Information Management System (RIMS) – A consultant is about to be appointed. September 2023
- Provision of Continental eCTD Solution – Awareness creation ongoing in all meetings

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Presentation by:

Kristiina Puussaari
eSubmission Programme Coordinator
EMA

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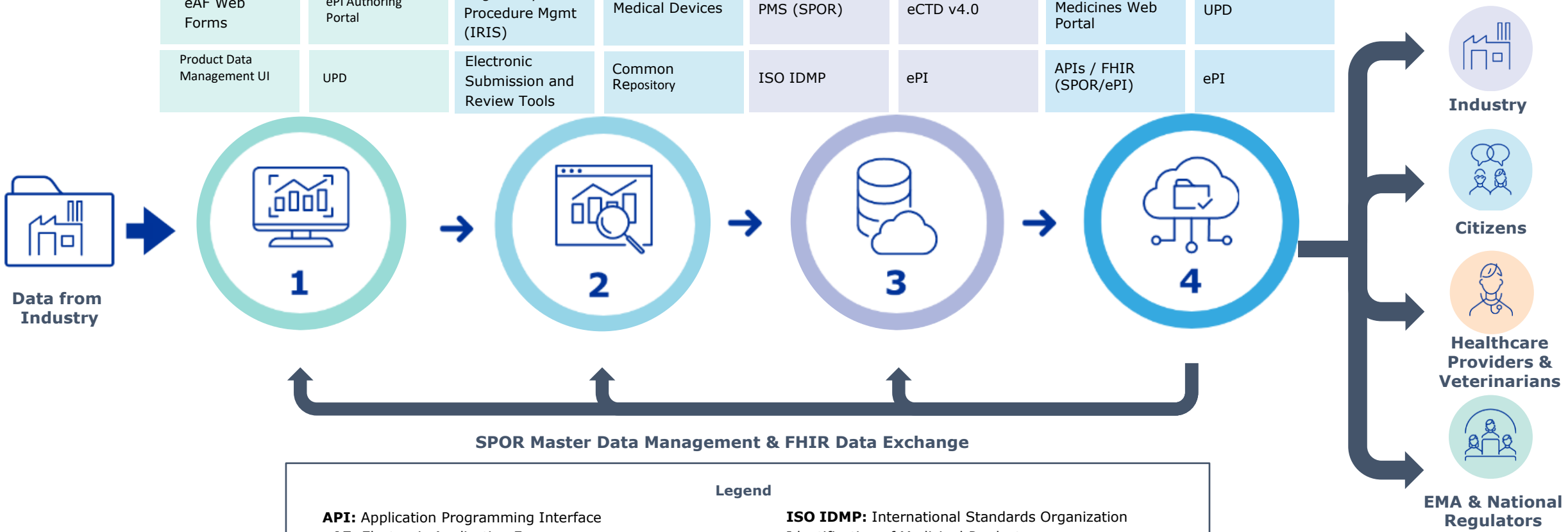
Product Lifecycle Management

A smoother and more coherent user journey

1. Capture data for regulatory processes		2. Validate, assess and analyse data		3. Store data using agreed standards		4. Share data & information across the lifecycle for customer value	
eAF Web Forms	ePI Authoring Portal	Regulatory Procedure Mgmt (IRIS)	Expert Panels for Medical Devices	PMS (SPOR)	eCTD v4.0	European Medicines Web Portal	UPD
Product Data Management UI	UPD	Electronic Submission and Review Tools	Common Repository	ISO IDMP	ePI	APIs / FHIR (SPOR/ePI)	ePI

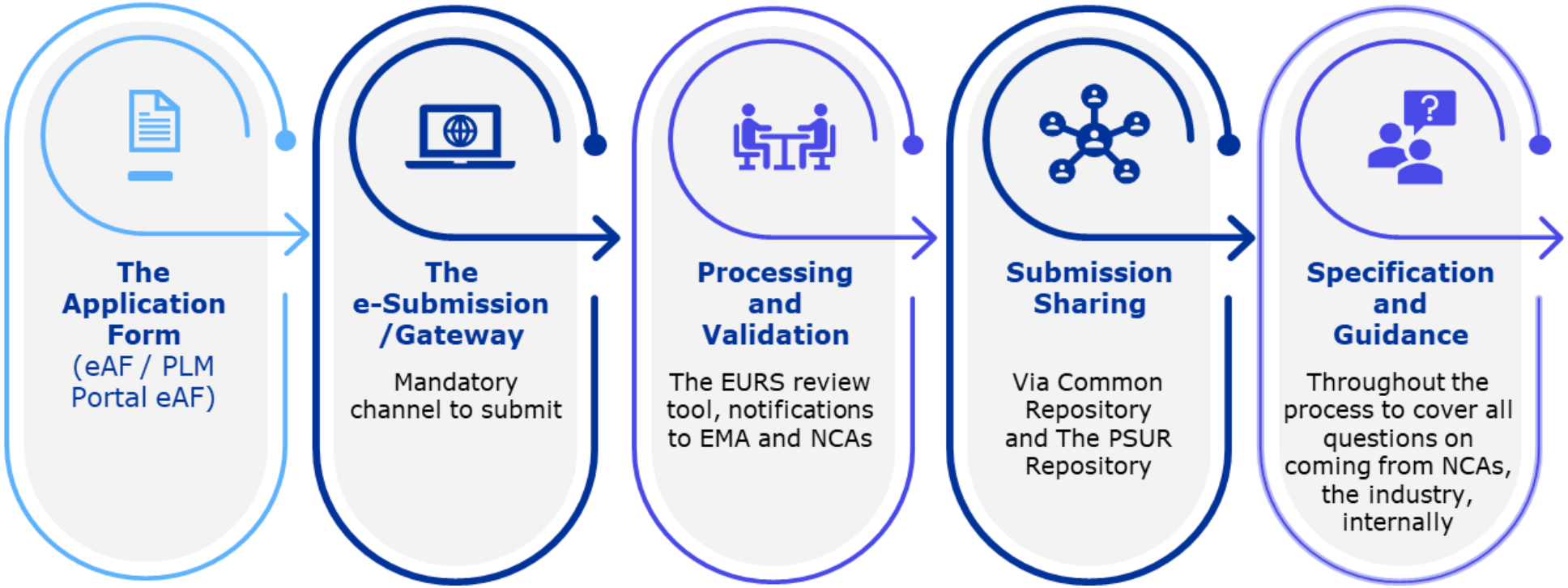


Legend

API: Application Programming Interface
eAF: Electronic Application Form
eCTD: Common Technical Document in electronic format
ePI: Electronic Product Information
FHIR: Fast Healthcare Interoperability Resources
ISO IDMP: International Standards Organization Identification of Medicinal Products
PMS: Product Management Service
SPOR: Substance, Product, Organisation and Referential
UPD: Union Product Database

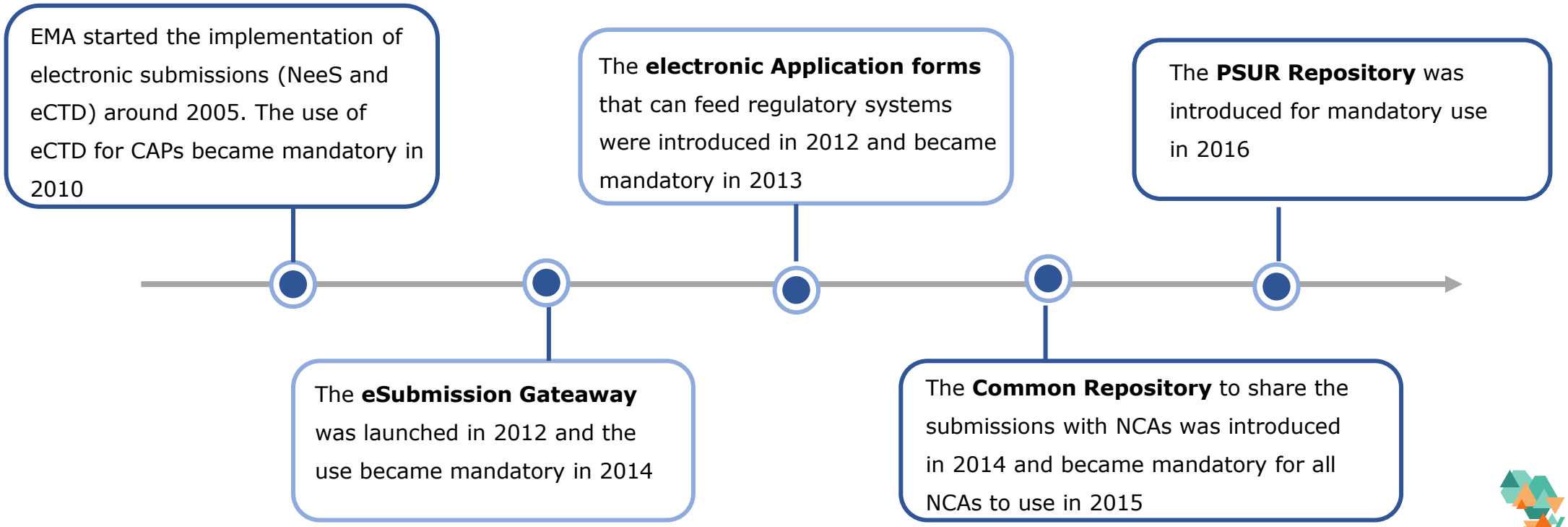
Electronic submissions (eSubmissions)

- With **eSubmissions** we create, enable, maintain and improve the submission tools and processes.
- eSubmissions support the EMAs core business and the whole EU network.



Electronic submissions (eSubmissions)

eSubmissions at the EMA have **organically grown** over nearly 2 decades, initially starting from non eCTD (NeeS and even non NeeS format) electronic submissions on CD/DVD replacing the huge pallets of files and folders that were sent to EMA and to each NCA



How did we do it successfully?

- The importance of **highlighting** the **benefits** to all stakeholders
- Importance of:
  - **Harmonised requirements** where possible to benefit from synergies
  - clear **regional specification**
  - **practical implementation** guides
  - Change Management and communication strategies in place ensuring timely communication to all stakeholders including channels for stakeholder communication to EMA (user groups, webinars, publications etc)
- Validation rules (for technical validation – automated rejection)
- Very clear **baseline requirements** (moving to eCTD from non-electronic/NeeS formats)
- Training for the **reviewers** – ensure readiness with **change management**

Next steps on the path of continuous improvement

- EMA has adopted **Agile methodology** and has moved the portfolio of projects to this new model. The main advantages is that EMA is now able to **bring value to stakeholders** faster and build that incrementally.
- Stepwise implementation of the **SPOR** (Substance, Product, Organisation, Referentials) **Programme** has enabled and facilitated the move to electronic Submissions
- EMA is constantly improving and expanding the **IRIS industry and network portals**, bringing move value and smoother and more streamlined user journey to stakeholders (following the new progressive release model).
- EMA has recently released the first version of the ePI with limited features that can be used by early adopters for Centrally Authorised Products and Nationally Authorised Products. This Minimum Viable Product is a ready-to-use product to be used in the business process, enabling creation of an ePI and update after positive opinion
- Ensuring interoperability by using common standards, for example HL7 FHIR (Fast Healthcare Interoperability Resources) standard

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Presentation by:

Christelna Reynecke
Chief Operations Officer
SAHPRA

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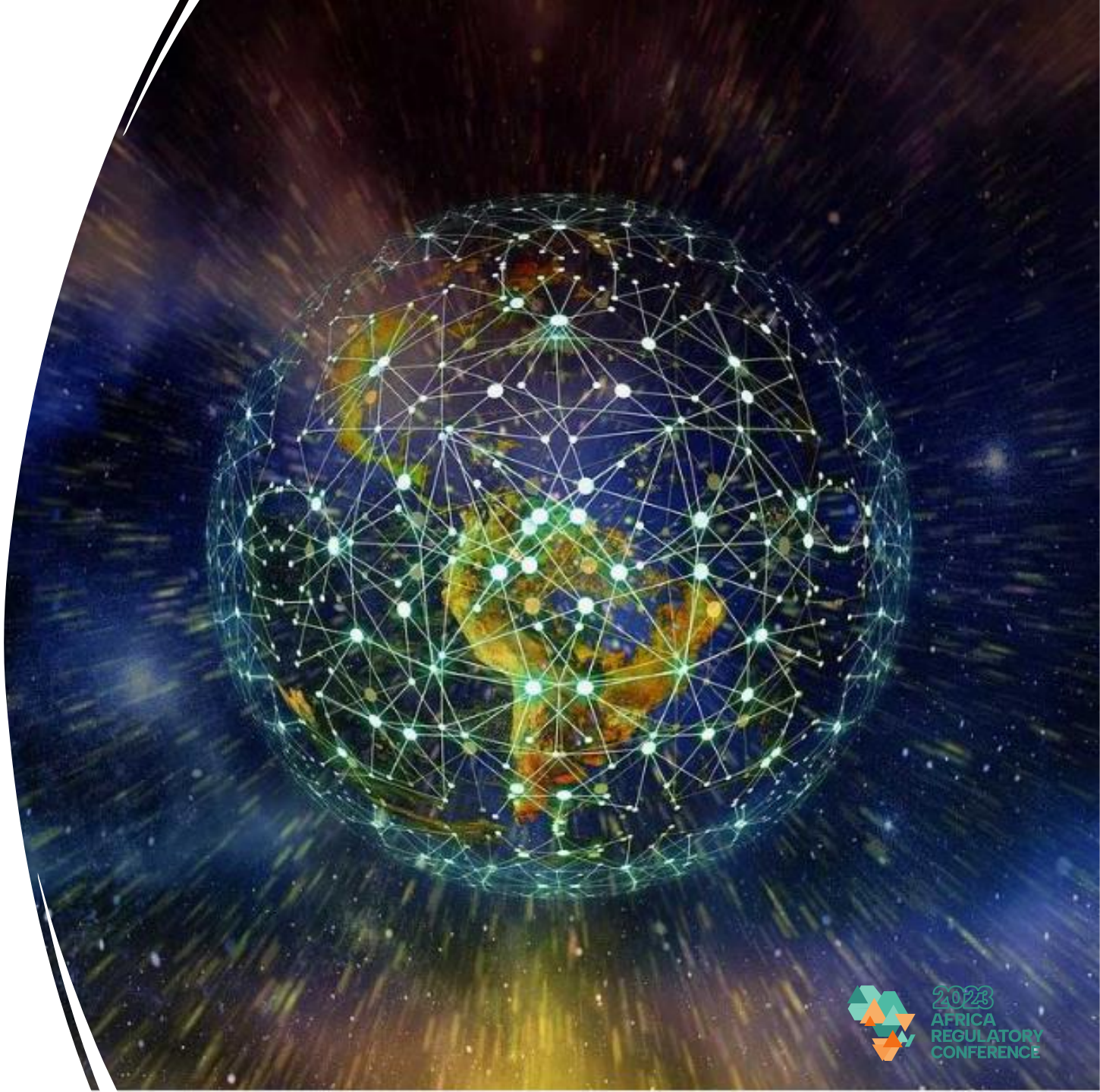
SAHPRA Digital Transformation

- SAHPRA's digital transformation is a priority for the organisation as our focus is on building the required capabilities, work processes and digital systems that will allow the institution to be more agile, innovative, streamlined, and efficient in the delivery of its mandate.

- At the centre of this digitisation will be an intuitive Single Sign On (SSO) self-service customer portal for the end-user, as well as intelligent internal management, automated workflows integrated with a review systems to streamline the entire regulatory process. Underpinned by a data analytics tool the enables real-time reporting and insights.d



Transformation Challenges

Digital Execution Maturity of the organization

Adequate funding support for Digital Tools and Change Management process

Competing Priorities

Deploying Integrated and Interoperable systems that will support seamless operational processing

4 Strategic Goals

ESTABLISH IT SERVICES AND INFRASTRUCTURE

CREATE AND IMPLEMENT ICT INFORMATION SECURITY FRAMEWORK

DIGITAL TRANSFORMATION OF THE ORGANISATION AND ITS BUSINESS PROCESSES

VALUE DELIVERY

Digital Transformation

- Where do we start?
- Business architecture
- Data architecture
- Application architecture
- Technology architecture
- Security architecture

ROADMAP


1
2019
1. ICT network infrastructure and connectivity, voice communication, collaboration and conferencing
2. First digital application portal deployed (DVP)
3. eCTD applications received via USB subsmission
2
2020
1. eCTD applications received via sFTP submission
3
2021
1. ICT Strategic Roadmap approved,
2. URS for RIMS developed and approved
3. Application portal for S21 applications
4
2022
1. Procurement of Customer Query management tool,
2. eQMS tool Phase I
3. Lot Release applications digitised
4. AEFI reporting analytics platform
5. MedSafety Application launched
6. Website navigation revamp
7. Website document library launch
5
2023
1. Import/Export Management portal
2. Health Product Renewal applications digitised
3. eQMS Phase II
4. Pilot New Health Product application digitisation tool
5. RIMS implementation PHASE I commences
6. URS for Pharmacovigilance developed
7. Clinical Trials MIS implemented
6
2024
1. RIMS PHASE II and full cut-over
2. Pharmacovigilance analytics tool
3. Self-Service applications portal with Payment gateway
4. Business Analytics framework and Tool
5. Organisational ERP solution - URS and Procurement
7
2025
1. Digital Tools integration completed
2. Business Analytics data interfaced with Key Stakeholders
3. Key performance metrics published to website

R-IMS Ecosystem

- **Stakeholder Engagement portal**
  - Self Service
  - Single Sign-on
  - Entry point for contact with the organization
    - Receive and manage customer queries
    - Receive and manage Health Product application submission
    - Receive and manage Establishment Licensing applications
    - Receive and manage recall notifications communications from applicants
    - Receive and manage annual reports – as required by conditions of registration
    - Receive and manage S21 and S36 applications
- **Health Product IMS**
  - Receive and process all manner of health product applications (eCTD formant, PFD format, IMDRF prescribed application format for Med Devices)
  - Document Management – for managing submitted dossiers in the relevant formats, validation the file structures and reporting on submission errors
  - Case Management – review reports, queries etc.
  - Lifecycle management of product (amendments)
  - Evaluator review tool
  - Resource management and planning tool

R-IMS Ecosystem

- **Clinical Trials Management tool**
  - Applications
  - GCP Inspections
  - Assessment feedback
  - Reporting requirements management
  - Safety Information management

- **Import/Export Permit management**
  - Management of sites
  - Management of country estimates and annual INCB reporting
  - Online application for import/export permits
  - Evaluation and evaluation results
  - E-Permit
  - Customs official online access to real-time information

R-IMS Ecosystem

- **Pharmacovigilance Ecosystem**
  - Reporting component – self reporting and healthcare practitioner reporting (AU 3S MedSafety)
  - Case Management component
  - Signal detection component
  - Analtytics and reporting component

- **Datawarehouse, Business Analytics and Stakeholder data management tool**
  - Data repository – interfaced with various software tools
  - Central data analytics center and dashboard reporting – management reports as well as select performance reports published to website for stakeholder review

- **Financial System upgrade**
  - ERP module to manage transactions, debtors, fees, payments, statements and financial reporting
  - Interfaced with Datawarehouse for key transactional prompts

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PANEL DISCUSSION

Teresa Eastwood-Kiefer
Chapter Leader, Regulatory Data and Content - **Roche**

Emmanuel Owusu Adasi
ICT Officer
Ghana FDA

Christelna Reynecke
Chief Operations Officer
SAHPRA

Tim Powell
Director, Submission Sciences - **Biogen**
Chair of the **EFPIA** eCTD Sub-Group

Kristiina Puussaari
eSubmission Programme Coordinator
EMA

Karim Kacimi
Regulatory Affairs Manager
Merck group
ALPI

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QUESTIONS AND ANSWERS

We encourage you to use the Q&A box to raise questions to the speakers.

If a question you would like to ask has already been raised, you can also “like” that question. "

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KEY TAKEAWAYS – AfRC Track 05

Great progress on digitalisation

Digitalisation is well underway in Africa thanks to the NRAs and RECs' advancements in digital innovations and eCTD deployments

No reinventing the wheel

Broaden the best practices across the continent by actively supporting the AMRH's endeavours for a centralized regulatory information management system and eCTD through the AMA.

Avoid putting the 'digital cart' before the 'digital horse'

A step-wise approach to the digitalisation journey is key to sustainable solutions. Foundational steps are critical for the AMA to participate in the future of regulatory digital transformation

Opportunity for AMA to leapfrog

AMA can leapfrog to the most modern solutions, avoiding pitfalls, outdated and siloed technologies others previously experienced.

Collaboration on the roadmap priorities

Industry is committed to partner on the digitalisation roadmap for the continent. We call on agencies and stakeholders to work together towards this goal through forums and pilots.

No 2-step Africa

AMA can connect all stakeholders in the continent and regulatory ecosystem layers. A strong, interoperable digital health infrastructure has the potential to help close disparities in access to care and help countries achieve their universal health coverage goals.

Virtual coffee/tea break

We will be back at **14h35 CEST**

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Transforming the Regulatory ecosystem in Africa

DAY 3 | How can Africa pioneer regulatory system innovation and digitalization?

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AfRC Track 06

Ability of regulatory systems to incorporate innovation and change

Session Moderator: **Ginny Beakes-Read**

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Regulatory Agilities Experienced by Industry in Africa, During the COVID-19 Pandemic

Presented by: **Jacqueline Acquah** (JnJ)

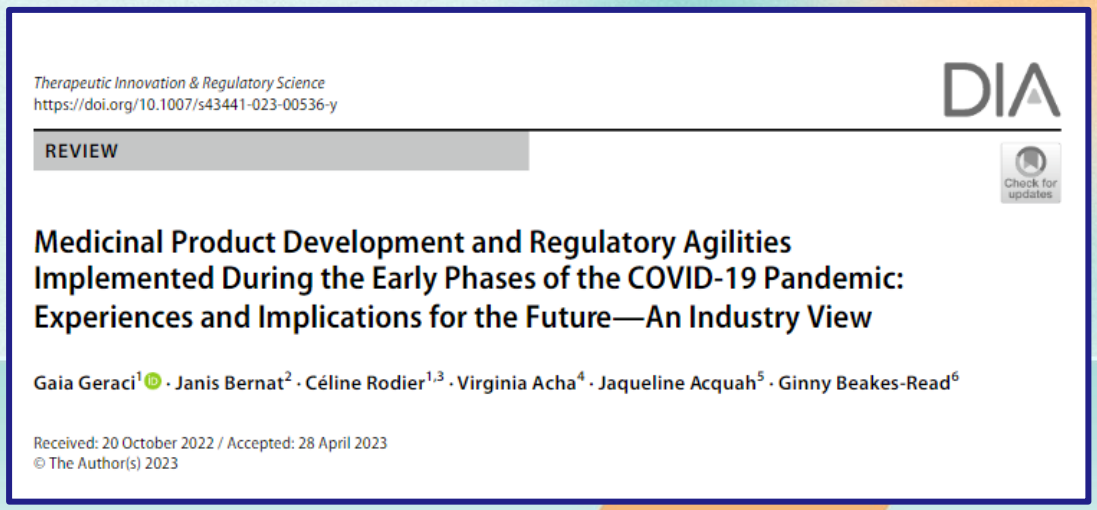
14 September 2023

IFPMA Research Project…

How should the industry and regulators prepare for future pandemics

Which of the regulatory agilities emerged with the COVID-19 pandemic could/should be integrated into the standard normative processes

…resulting in the following publication.



Therapeutic Innovation & Regulatory Science
https://doi.org/10.1007/s43441-023-00536-y

DIA

REVIEW

Medicinal Product Development and Regulatory Agilities Implemented During the Early Phases of the COVID-19 Pandemic: Experiences and Implications for the Future—An Industry View

Gaia Geraci[1] · Janis Bernat[2] · Céline Rodier[1,3] · Virginia Acha[4] · Jaqueline Acquah[5] · Ginny Beakes-Read[6]

Received: 20 October 2022 / Accepted: 28 April 2023

Regional Overview of Africa ~ Trends

Regulatory Processes

- Use of Reliance
- Use of Digital and e-tools
- Prioritization of renewals and PACs to ensure supply of already approved products .
- Use of waivers for some regulatory processes

Clinical Trials

Not much documentation on agilities on clinical trials in Africa

Quality

- Risk-based GMP Certification
- Use of e-documents like e-CPP, and reduced product-release requirements in some cases
- Virtual/Hybrid Inspections

Regional Overview of Africa ~ Challenges

Fragmented regulatory systems.

Non-existent or limited digital infrastructure in most cases, resulting in Use of hard copy, physical submissions , rather than e-submissions in some cases.

Unpredictable timelines as seen with general delays in new product registrations, GMP renewal and import permit validation and issuance.

No framework for the use of reliance or where a framework is present, reliance not utilized effectively.

Virtual meetings not always possible.

Limited resources, including human resource and capacity and testing equipment.

Requirement for legalized documents, samples for initial registrations and post approval changes in some cases

How can Africa prepare for the future?

STANDARD NORMATIVE PROCESS

Overall

- Achieve **common standards** for all medicines in the continent.
- **Increase digitalization and use of electronic tools**: email communication; virtual meetings; e-platforms; electronic documents (e.g. CPP).
- **Leverage digitalization** to avoid losing documents and enable reliance and use of work from different jurisdictions.
- Integrate **reliance practices** into the operations of the NRAs and decision-making process.
- **Increase reliance and transparency.**
- Develop an **ecosystem facilitating sustainable business and local production.**

Regulatory

- **Institutionalize expedited regulatory pathways** at country, regional and continental level: including priority review, fast tracked reviews for selected types of products, temporary authorizations of products for emergency use.
- **Adopt or increase work-sharing, joint assessments and reliance** as part of the decision-making process, consider this in light of the set up of AMA.
- Introduce **flexibilities** for high unmet need and "high profile" products as a priority, and all products if possible.

Quality

- **Institutionalize use of eCPPs**, soft copies of other administrative documents (e.g. GMP / Manufacturing license) as new way of working when possible.

Clinical trials

- Ensure **rigorous review and processes**.

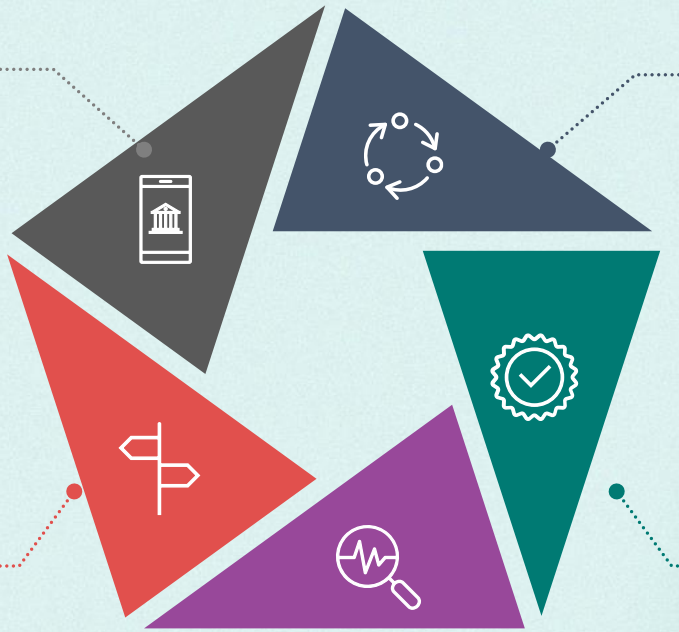
CPPs: Certificate of Phamaceutical Products. NRA: National Regulatory Authority. GMP: Good Manufacturing Practice. AMA, Africa Medicines Agency. PAC: Post Approval Change. GRP: Good Regulatory Practices.

Conclusion

The regulatory dialogue should be iterative, responsive, holistic and voluntary in the future.

Strong political will facilitates changes to regulatory frameworks for the benefit of patients.

Consider regional differences and leverage local trade & patient organizations for advocacy purposes, as needed



DIGITALIZATION
Institutionalize virtualization of ways of working, use of digital formats

RISK-BASED APPROACHES
To be adopted in decision-making

PACs MANAGEMENT
Prioritize Post-approval changes management to allow fast manufacturing and supply

RELIANCE, WORK-SHARING AND ALIGNMENT
Increase collaboration for efficiency gain

NRA: National Regulatory Authority.

THANK YOU!

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12–15 SEPTEMBER | VIRTUAL CONFERENCE

TOGETHER FOR PATIENTS

Transforming the Regulatory ecosystem in Africa

Presented by: **Edwin Nkansah**, Director, Vaccine, Vigilance and Clinical Trials Directorate, FDA Ghana

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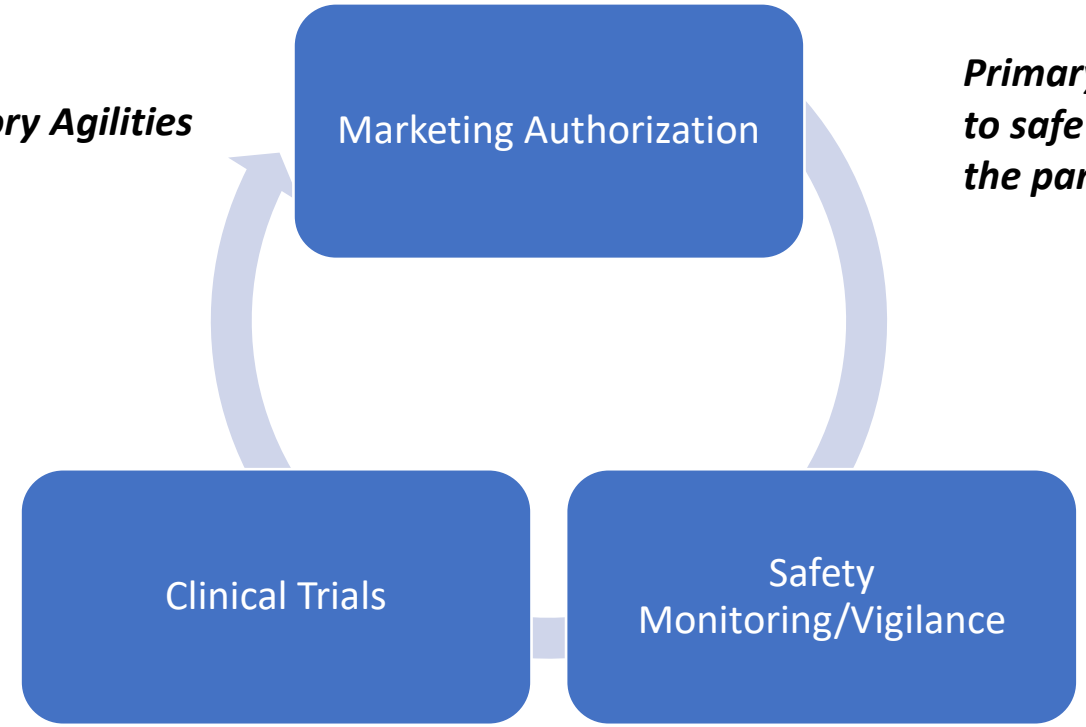
NRA PERSPECTIVES ON USE OF REGULATORY AGILITIES AND IMPLICATIONS FOR THE FUTURE

Food and Drugs Authority: Is the National Regulatory Authority responsible for the regulation of Health Products and Technologies, post-authorization safety monitoring of regulated products and clinical trials oversight.

Regulatory Agilities



Primary goal was to ensure rapid access to safe and effective products to combat the pandemic.

FOOD AND DRUGS AUTHORITY
FDA
GHANA
Your Well-being, Our Priority.

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AGILITIES APPLIED TO THE CLINICAL TRIALS FUNCTION

CLINICAL TRIAL OVERSIGHT:

- ***Expedited CTA processing***: Revised CTA processing timelines to 21 working days -original timelines of 60 days – to expedite processing CTA submitted towards decision making in during the pandemic or public health emergency.
  - Other CTA application which may be deemed critical towards urgent decision making may be subjected to this expedited pathway
- ***Reliance***: Leveraging reliance to process CTAs – rely wholly or partly on the decision made by a well-resourced NRAs
  - Decisions made on the Protocol/IMPD/IB, etc
- ***Virtual training***: Revised the GCP training format from in-person face-to-face to virtual to promote the ease of participation.
  - Improved participation in terms of numbers (well of 350 participants enrolled for the second 2023 training programme)
- ***Concurrent submission***: Concurrent submission of CTA and ECA to promote parallel processing of applications
  - Shortened the timelines for regulatory decision making…
- ***CTA for Herbal Medicine***: Receipt, evaluation and approval of a CT for of a locally manufactured herbal product for the treatment of COVID-19 disease. Current requirements amended to receive and process such applications
  - Study outcome: Reasonable sample size not attained –
- ***Adoption of new CT designs***: Adoptive trials received and approved

AGILITIES APPLIED TO THE MARKETING AUTHORITY FUNCTION

MARKETING AUTHORIZATION:

- ***Application of Reliance***: policy allowed application to be processed via an alternative processing pathway which allowed expeditious evaluation of submitted application towards decision making – leveraging decisions made by a well-resourced NRA, WHO, regional bodies such as WAHO, etc.
  - Applied the reliance policy of FDA
- ***Classification of evaluation queries***: Queries are classified into **Critical** (*requirements shall be satisfactorily addressed before authorization shall be granted*) and **Major** (*requirements shall be satisfactorily addressed during period of the authorization*) to unnecessarily hinder market entry of a life-saving drugs;
- ***Rolling submission*****:** allowed continuous submission and subsequent review of data on on-going studies towards regulatory decision making ;
  - allowed companies to submit data subsequently to complement already submitted applications to support decision making.
- ***Dedicated review team*****:** dedicated teams of experts to review applications deemed to be of public health concerns;
  - Team – Joint review team – convened as and when necessary to expeditiously review and make recommendations on application. Decision making within 15 working days.

AGILITIES APPLIED TO THE MARKETING AUTHORITY FUNCTION

- ***Virtual dossier evaluation meeting*:** In-person face-to-face committee meetings to partly or wholly virtual meetings to evaluate product development dossiers towards MA.

- ***Conditional Authorizations****:* application of conditional authorizations – limited validity (1 year instead of the standard 3 years) – extended upon satisfactory evaluation outcome of submitted condition(s) – mostly bothering on product safety and efficacy (post-approval requirements).

*It's important to note that while these interventions were crucial in addressing the urgent need for life-saving medical products, the FDA maintained a commitment to **safety** and **efficacy** standards.*

- Authorizations comes with rigorous monitoring, post-market surveillance, and directive/commitment to submit data collection studies (*if necessary*)

AGILITIES APPLIED TO THE VIGILANCE FUNCTION

- Rapid deployment of expert committees leveraging existing expert committees (*i.e.,* medicines, and vaccine and biological products, medical devices, food and nutrition)
  - *e.g.,* establishment of the 11-member Joint COVID-19 Vaccine Safety Review Committee during the pandemic..
- Conversion of in-person face-to-face meeting/activities to virtual meetings/activities
  - Virtual PV sensitizing trainings
  - Virtual meetings of expert committees to assess ADR/AEFI/SAEs
- Active follow-up study (cohort event monitoring) to identify safety issues.
  - Applicable whenever we grant authorization to a product of interest with limited safety information…

THANK YOU!

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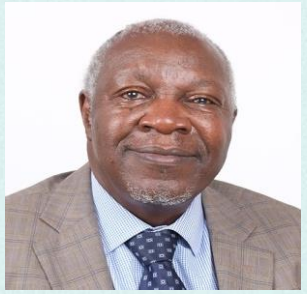
Associations' Perspectives

Ginny Beakes-Read
Vice President,
Global Regulatory Policy & Intelligence
Janssen Inc.

Nicholas Cappuccino
Chair, Science Committee
IGBA



Wilberforce Wanyanga
Board Member,
FAPMA

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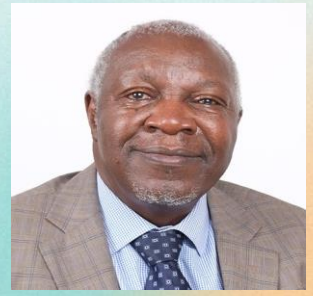
PANEL DISCUSSION

Ginny Beakes-Read
Vice President,
Global Regulatory Policy & Intelligence
Janssen Inc.

Jacqueline Acquah
Associate Director,
Global Public Health
Vaccines Regulatory
Affairs (EMEA),
Janssen

Edwin Nkhansah
Director,
Vaccine, Vigilance and
Clinical Trials
Directorate,
FDA Ghana

Nicholas Cappuccino
Chair, Science
Committee
IGBA



Wilberforce Wanyanga
Board Member,
FAPMA

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QUESTIONS AND ANSWERS

We encourage you to use the Q&A box to raise questions to the speakers.

If a question you would like to ask has already been raised, you can also “like” that question. "

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KEY TAKEAWAYS – AfRC Track 06

- Initially, the **primary goal of regulatory agilities** was to ensure rapid access to safe and effective products to **combat the pandemic**. Now there is an opportunity to review and incorporate regulatory agilities within normal regulatory processes to **promote innovation & advancement in regulatory systems**.
- Use of **reliance, digitalization, e-tools/e-documentation and collaborative hybrid virtual inspections** stand out as areas for implementation and growth.
- Regulatory agilities have the possibility to accelerate processes, yet commitments to **quality, safety and efficacy** must be maintained for the benefit of patients.

THANK YOU!

Join tomorrow for AfRC Day 4

How do patients benefit from stronger regulatory systems?

13:00 -16:00 CET

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