CDER SBIA DMF Workshop: GDUFA III Enhancements and Structured Data Submissions

Cloud-based Regulatory Submission and Assessment: ICH M4Q(R2) and FDA KASA Initiative

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Pharmaceutical Quality

- A quality product of any kind consistently meets the expectations of the user – drugs are no different
- Patients expect safe and effective medicine with every dose they take
- Pharmaceutical quality is assuring every dose is safe and effective, free of contamination and defects
- It is what gives patients confidence in their next dose of medicine

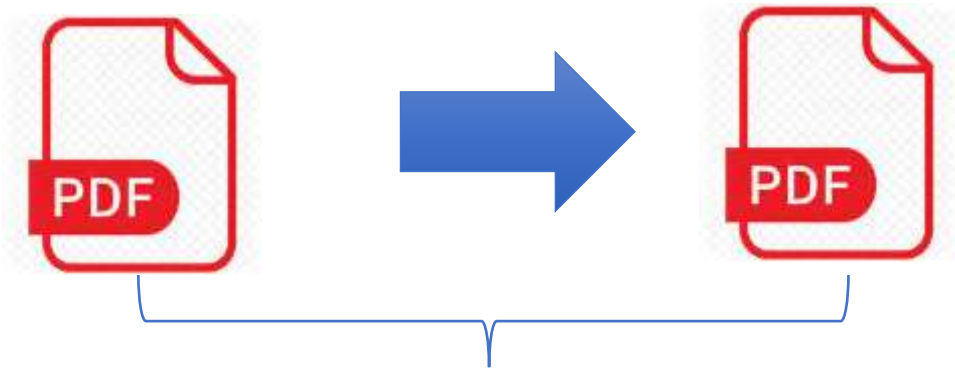
Current Regulatory Submission and Assessment

Applicant

Submission

Health Authority Gateway

Assessment



Health Authority Local Server

Characteristics: Lengthy unstructured text narrative with dispersed information and the lack of efficient information sharing, knowledge management, and data analytics

FDA's Pharmaceutical Quality Assessment is Moving into Cloud

Applicant

Health Authority Gateway

Submission

PDF

Health Authority Local Server

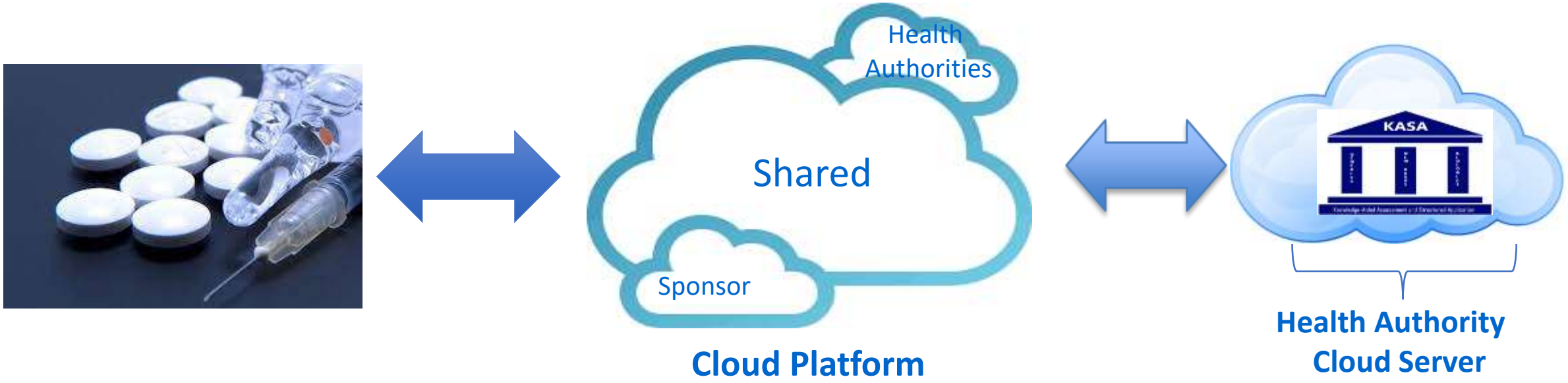
Assessment

Health Authority Cloud Server

Characteristics: Lengthy submission with unstructured text narrative and the lack of efficient information exchange. Regulatory assessment moves to structured data enabling efficient information sharing, knowledge management, and data analytics, resulting efficient regulatory assessment

Future Regulatory Submission and Assessment

Applicant **Submission** **Assessment**



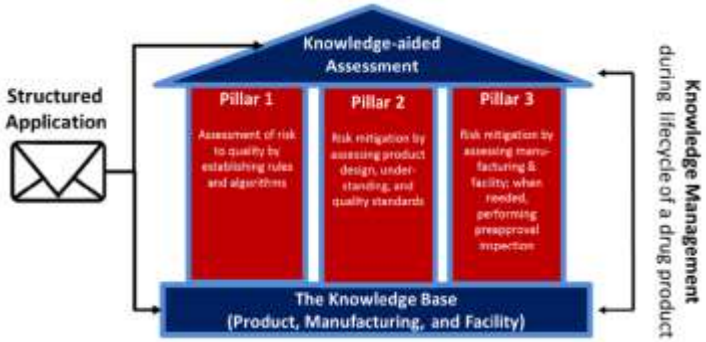
Characteristics: Both regulatory submission and assessment move to structured data format enabling efficient regulatory submission and assessment, information sharing, knowledge management, and data analytics

How to Get There?

- Regulatory Assessment Transformation
  - ➢Knowledge-aided Assessment and Structured Applications (KASA)
- Regulatory Submission Transformation
  - ➢Revision of ICH M4Q
  - ➢Pharmaceutical Quality electronic data standards

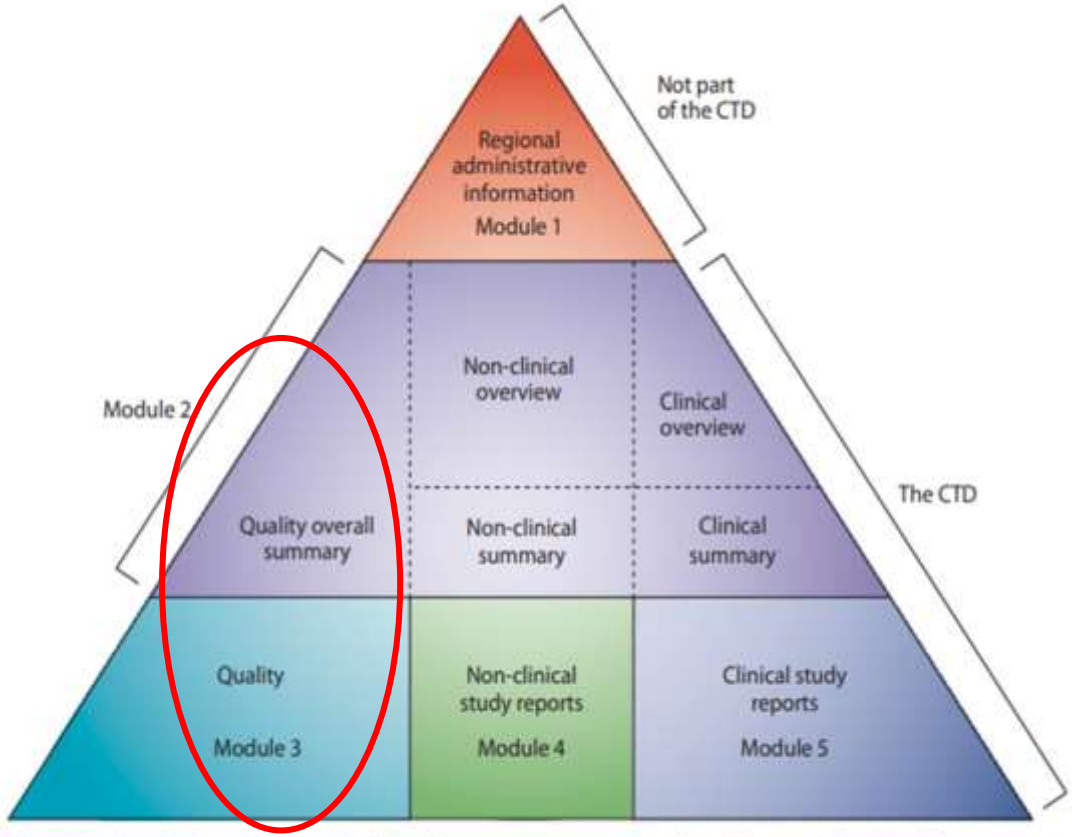
FDA KASA: Vision

- In 2016, FDA's KASA system was envisioned as a means of modernizing FDA's assessment (or review) by taking advantage of:
  - Structured data (as opposed to narrative information)
  - Advanced analytics; and
  - Knowledge management



ICH M4Q Guideline

- Provides a harmonized structure and format for presenting quality information in Common Technical Document (CTD)/electronic CTD for registration of pharmaceuticals for human use
  - **Module 2 Quality Overall Summary (QOS)**
  - **Module 3 Quality**
- ICH is making transformational changes of M4Q to facilitate cloud-based regulatory submission



The CTD triangle. The Common Technical Document is organized into five modules. Module 1 is region specific and modules 2, 3, 4 and 5 are intended to be common for all regions.

ICH The Common Technical Document for the Registration of Pharmaceuticals for Human Use: Quality M4Q(R1) Quality overall Summary of Module 3, Module 3: Quality, September 2002
FDA Guidance for Industry M4Q: The CTD – Quality, August 2001

Structured Quality Data Submission

Future Data Submissions and Assessment

Pharmaceutical development
and product lifecycle management

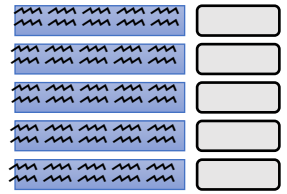
Applicant

Module 2

Module 3

CMC information and
data repository

Regulatory
Quality
Assessment



FDA Acronyms & Abbreviations

Version 2 – Updated September 28, 2022

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Thank You


Effective leadership
Collaborative relationships
Encourage innovation
Risk-based approaches
One Quality Voice
Patients first
Team-based processes
Developing and utilizing staff expertise
Scientifically-sound quality standards