

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

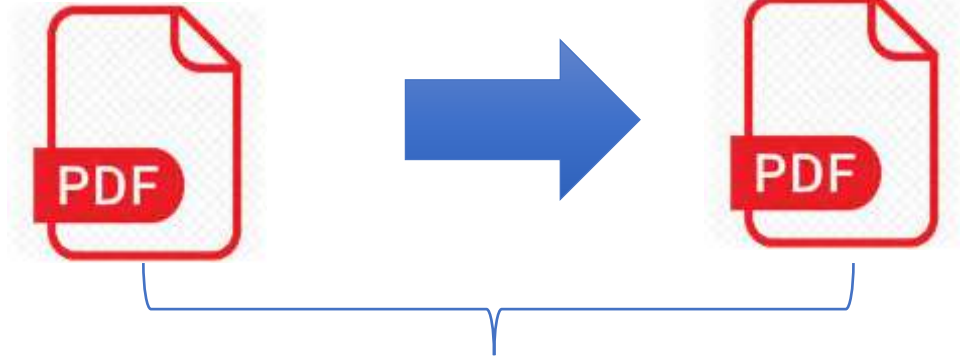
Applicant



Submission



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



Submission



Health Authority
Local Server

Assessment



Health Authority
Cloud Server

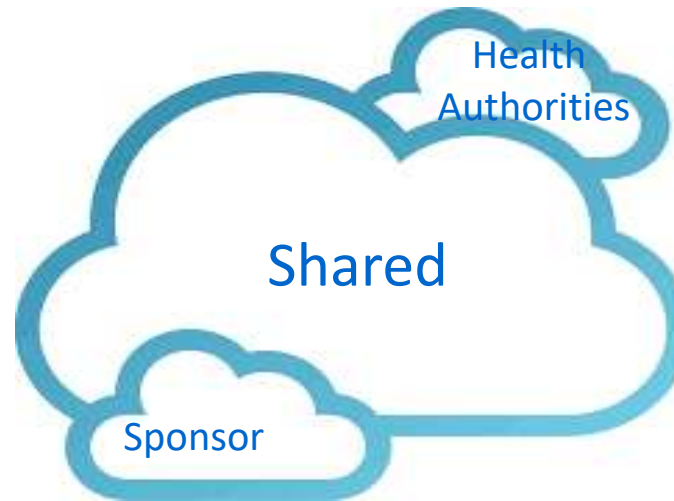
Characteristics: Lengthy submission with unstructured text narrative and the lack of efficient information exchange. Regulatory assessment moves to structured data enabling efficient information sharing, knowledge management, and data analytics, resulting efficient regulatory assessment

Future Regulatory Submission and Assessment

Applicant



Submission



Cloud Platform

Assessment



Health Authority Cloud Server

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

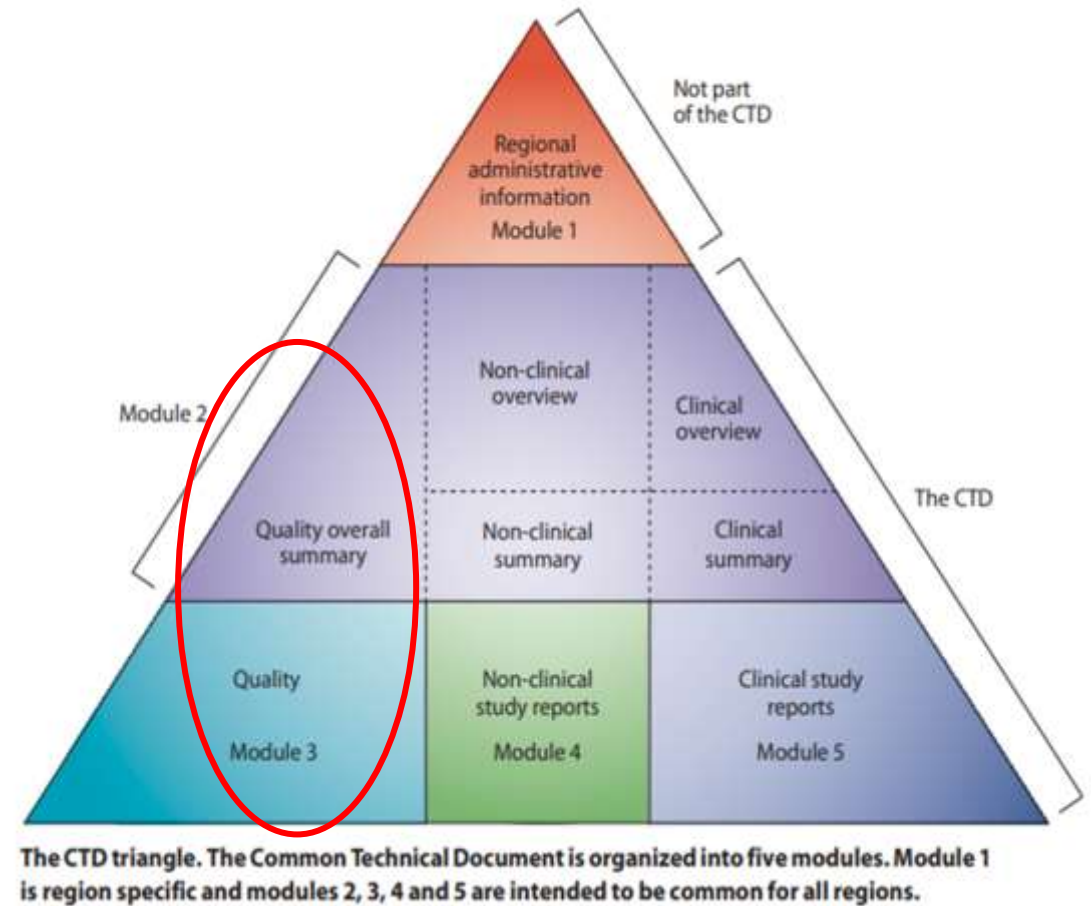


- In 2016, FDA's KASA system was envisioned as a means of modernizing FDA's assessment (or review) by taking advantage of:
 - Structured data (as opposed to narrative information)
 - Advanced analytics; and
 - Knowledge management



ICH M4Q Guideline

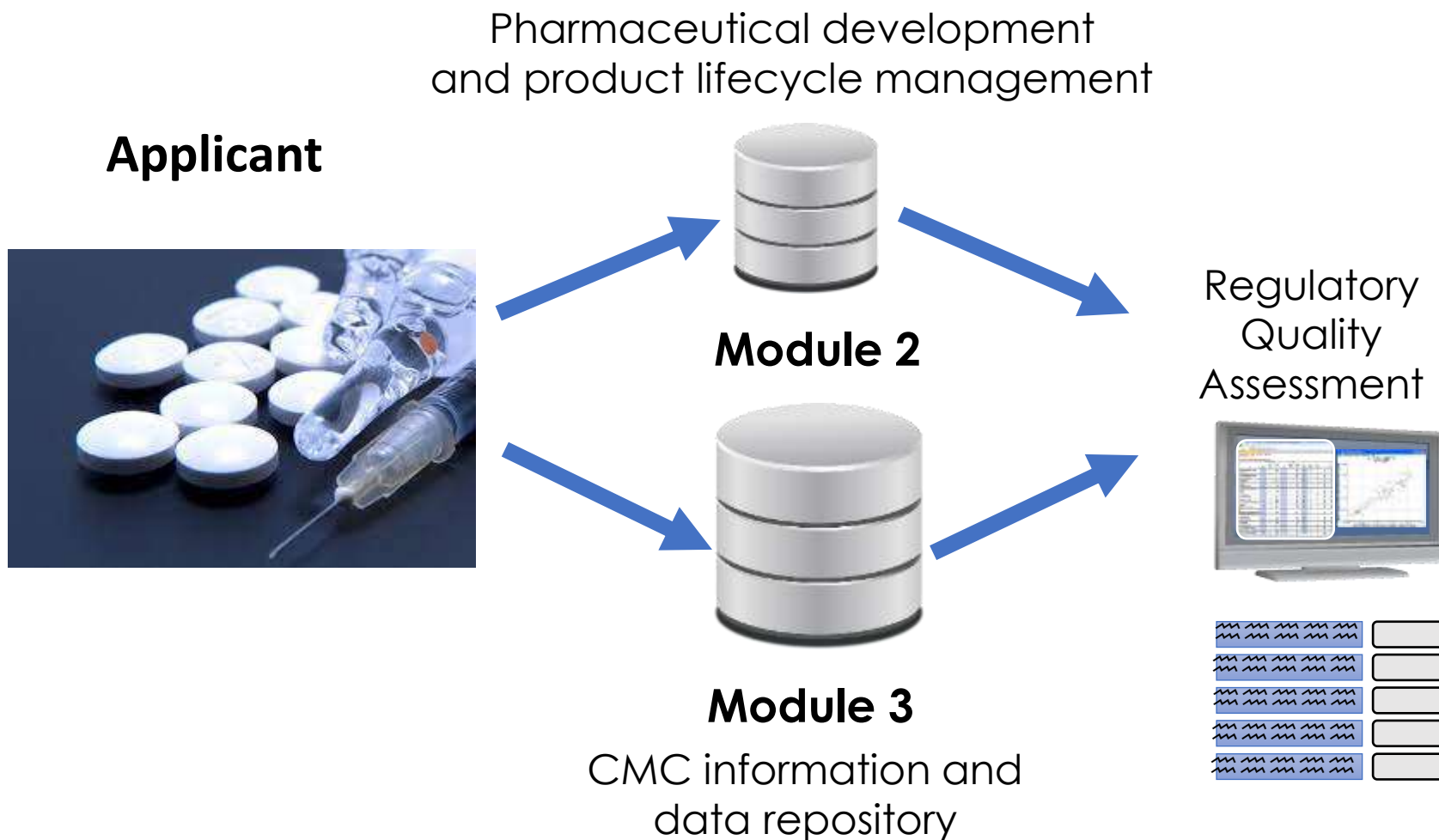
- Provides a harmonized structure and format for presenting quality information in Common Technical Document (CTD)/electronic CTD for registration of pharmaceuticals for human use
 - **Module 2 Quality Overall Summary (QOS)**
 - **Module 3 Quality**
- ICH is making transformational changes of M4Q to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



Structured Quality Data Submission



Future Data Submissions and Assessment



CDER SMALL BUSINESS AND INDUSTRY ASSISTANCE (SBIA)

**DMF WORKSHOP:
GDUFA III ENHANCEMENTS and
STRUCTURED DATA SUBMISSIONS**



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NOV 30, 2022

Version 2 – Updated September 28, 2022

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AGENDA

All times are Eastern (EDT UTC-4)

[View Start Time on World Clock](#)

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