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FDA Perspectives on ICH E6(R3): Driving Clinical Trial Quality Through Quality by Design

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FDA Perspectives on ICH E6(R3): Driving Clinical Trial Quality Through Quality by Design

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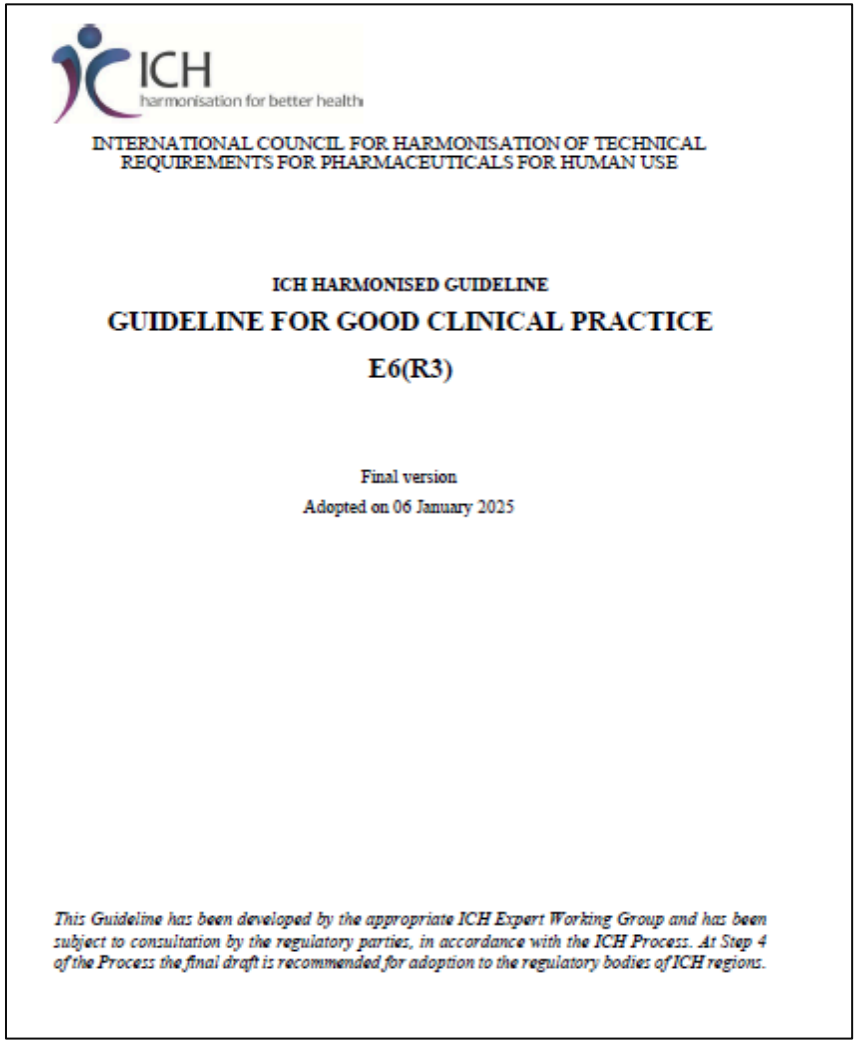
Disclaimer

- The views and opinions presented here represent those of the speaker and should not be considered to represent advice or guidance on behalf of the U.S. Food and Drug Administration

Overview for Today's Presentation

- Highlight factors for successful implementation of ICH E6(R3)
- Explore core principles of quality by design, risk proportionality and fit-for-purpose clinical trial quality in ICH E6(R3) which are reshaping how we design and conduct clinical trials
- Highlight international regulatory collaboration efforts that are driving harmonized inspection practices and consistent inspection standards across global regulators



ICH
harmonisation for better health

INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED GUIDELINE

GUIDELINE FOR GOOD CLINICAL PRACTICE

E6(R3)

Final version

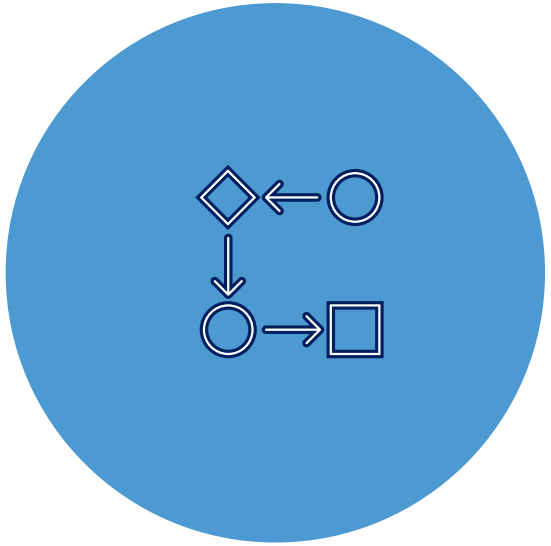
Adopted on 06 January 2025

This Guideline has been developed by the appropriate ICH Expert Working Group and has been subject to consultation by the regulatory parties, in accordance with the ICH Process. At Step 4 of the Process the final draft is recommended for adoption to the regulatory bodies of ICH regions.

Translating E6(R3) into Action: Success Factors for Implementation

Cultural/Mindset Shift

+

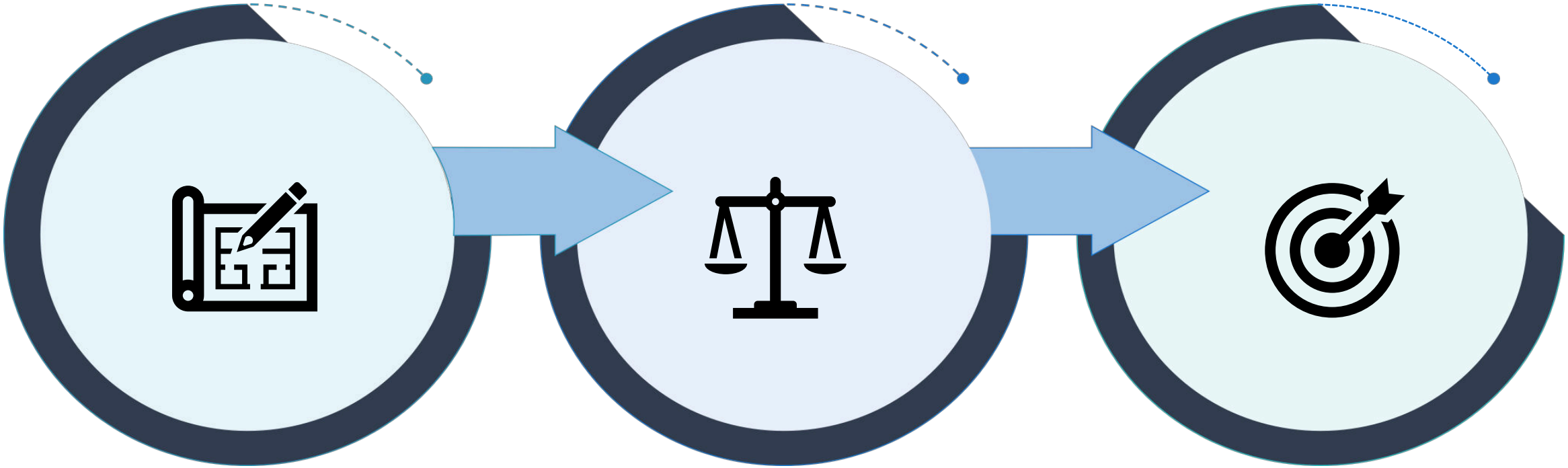


Policy Alignment

=

Successful E6(R3) Implementation

Foundational Concepts in ICH E6R3



Quality by Design (Principle 6)

Risk Proportionality (Principle 7)

Fit-for-Purpose Clinical Trial Quality (Principle 9)

Principle 9: Fit-for-Purpose Clinical Trial Quality

The trial's objectives are met

+

The trial is of sufficient quality to provide confidence in the trial's results and to support good decision-making

+

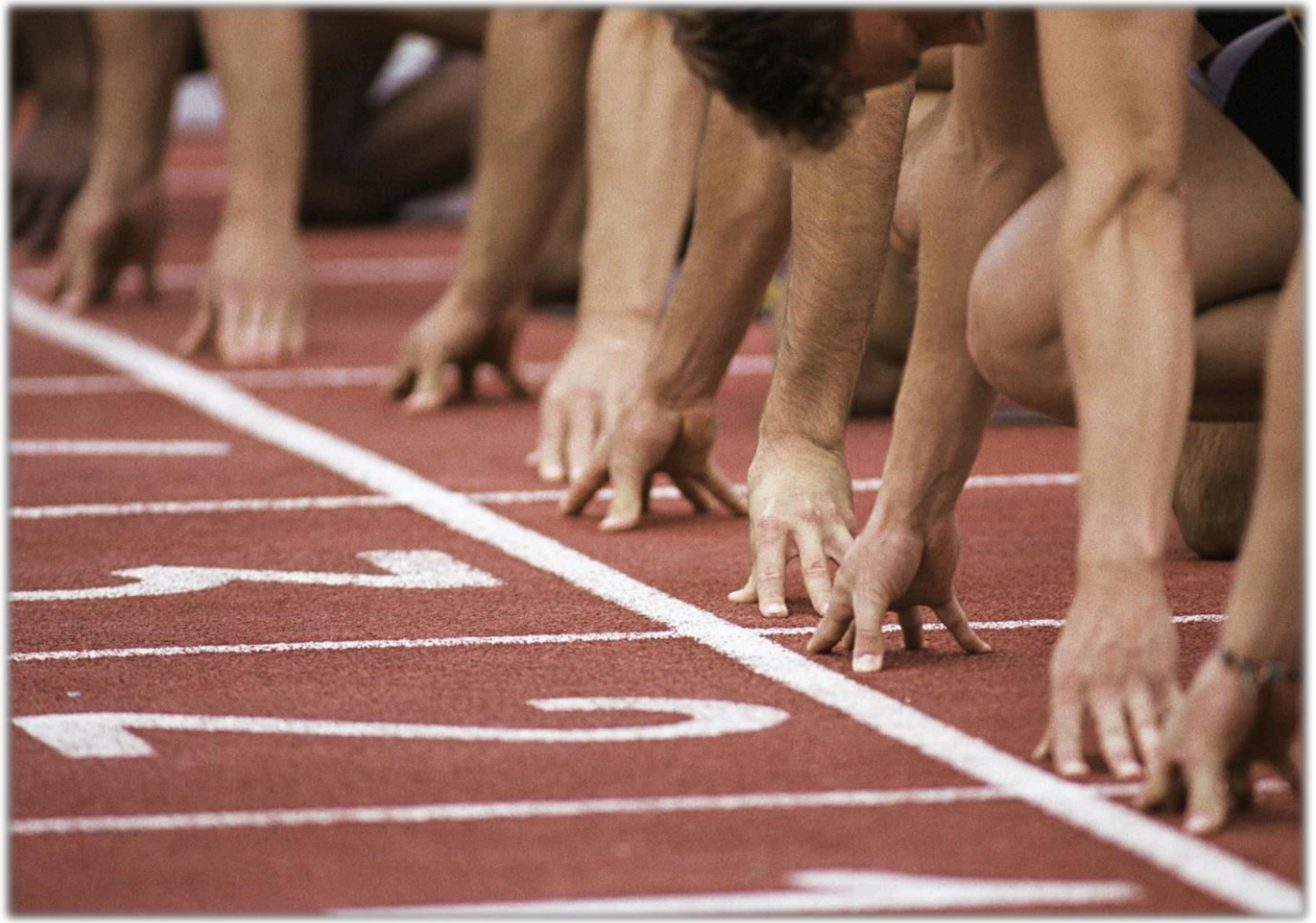
The rights, safety, and well-being of trial participants have been adequately protected

=

Fit-for-Purpose Clinical Trial Quality

Principle 6: Quality by Design

- You do not rise to the level of your goals. You fall to the level of your systems.
  - James Clear (Atomic Habits)



Principle 7: Risk Proportionality

Risk Proportionality	Sponsors Responsibilities
• Applies to all types of trials and within various domains of clinical trial design and conduct (e.g., quality management, trial oversight, data governance) • Ensures that the level of resources applied to managing risks to clinical trial quality is commensurate with the potential importance of those risks to participants' rights, safety, and well-being and the overall trial results	• Conduct risk assessments during trial design to integrate risk-based strategies effectively • Prioritize resources and implement targeted strategies for high-risk areas (e.g., more intensive reviews/oversight for critical data and processes) • Ensure trial plans and processes (e.g., monitoring, rb-CDM) align with QbD approach • Evaluate CTQ factors and risks throughout trial conduct, communicate risks, document actions taken, and ensure corrective measures are reflected in the CSR

Why Adopting a QbD Approach Matters

Enables streamlined trial design and conduct

Reduces the likelihood of problems arising during the trial, enhancing the overall quality and reliability of the trial

Facilitates more efficient and focused use of resources

Transparent framework has the potential to enhance trust with regulatory agencies

FDA Requirements: Clinical Trial Quality

- Approving a New Drug: Two Components

Demonstrating effectiveness: meeting the substantial evidence standard

and

Concluding that the drug's benefit outweighs its risk: how FDA interprets "safe for use…."

How Does the QbD Framework Get Us to an AWC Study

There is a clear statement of objectives of the investigation and methods of analysis

Assure that the study design elements and study conduct focus on the key objectives: avoid unnecessary complexity

The study uses a design that permits a valid comparison with a control to provide a quantitative assessment of drug effect: *placebo-control, dose-comparison control, no treatment control, active-treatment control, historical control*

Select a study design that can properly address the study objectives – and accounts for other key criteria needed for study interpretability

The method of selection of subjects provides adequate assurance that they have the disease/condition being studied.

Keep the enrollment criteria as broad and simple as possible—but assure that the population is consistent with the study objective

The method of assigning patients to treatment and control groups minimizes bias and is intended to assure comparability of the groups with respect to pertinent variables.

Assure the selected study design is fit-for-purpose: can the comparison group assure an interpretable result?

Adequate measures are taken to minimize bias on the part of the subjects, observers, and analysts of the data

If blinding is not feasible, assure that the study design, conduct, and analysis can still provide interpretable results

The methods of assessment of subjects' response are well defined and reliable

Assure the endpoint is reliable and fit-for-purpose in addressing the study objective

There is an analysis of the results of the study adequate to assess the effects of the drug

Prespecify the approach to avoid Type I error, and assure that the analytic method provides interpretable results

FDA Requirements: Clinical Trial Quality

21 CFR 314.126 broadly describes what constitutes an AWC study

Is the primary basis for determination of whether “substantial evidence” has been provided to support the claims of effectiveness for new drugs

Closest FDA regulatory requirement that describes expectations for clinical trial quality

Why Adopting a QbD Approach Matters

- Enables focus on the key regulatory "currency" to support regulatory decisions - the regulatory criteria for an adequate and well controlled investigation (see 21 CFR 314.126)

Key Challenges in Adopting a QbD Approach

Cultural Shift

- Transitioning from a reactive quality management approach to a proactive one that begins in the design phase, tailoring processes to the unique design and objectives of each trial
- Adopting a multidisciplinary and cross-functional approach to trial design and planning, integrating diverse expertise and perspectives from the outset

Implementation Complexity

- Integrating QbD principles with existing clinical trial frameworks and industry practices
- Aligning QbD strategies with service providers, CROs, and clinical investigators to ensure consistency and collaboration

Regulatory Uncertainty

- Navigating interpretations regarding what is CTQ for each trial and ensuring alignment with regulatory authorities to maintain compliance across regions
- Inspection practices may lack full alignment with the risk-based framework, creating inconsistencies in regulatory oversight and expectations across regions

www.fda.gov

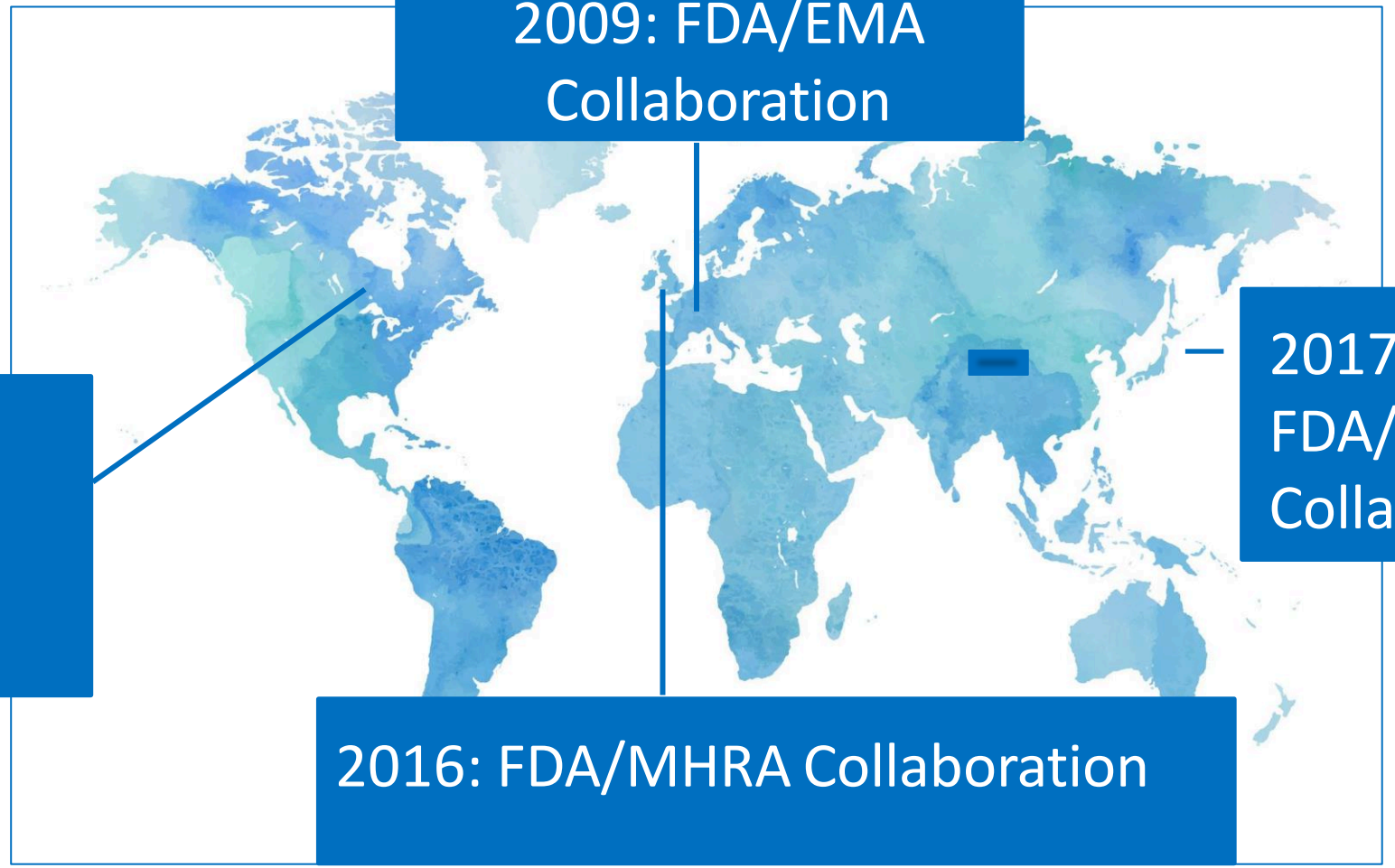
Aligning Inspection Practices with Risk-Proportionate Approaches

External stakeholder feedback has highlighted fears of inconsistent inspector interpretation of risk-proportionate approaches

Sponsors have expressed hesitation to adopt E6(R3)'s risk-based framework fearing misalignment with inspection expectations

Modernizing GCP requires evolving inspection practices that enable inspectors to confidently and consistently evaluate trials within the E6(R3) risk-based framework

International Collaboration



Pharmaceutical Inspection Co-operation Scheme (PIC/S) GCP Expert Circle

- Non-binding partnership of 56 regulatory authorities
- Aims to harmonize inspection standards worldwide
- Expert Circle on GCP (est. 2022)
  - Focused on training and practical guidance for GCP inspections
  - Promotes a harmonized, consistent inspection approach
- Mission
  - To support efficient, risk-based regulatory oversight
  - To align inspection practices with ICH E6(R3) principles
  - To promote a framework where inspection activities focus on the trial's CTQ factors

Key Take Home Points

Three Core Principles to Drive Quality:

- QbD and critical to quality factors
- Risk Proportionality
- Fit-for-Purpose Clinical Trial Quality

Keys to Successful Implementation:

- Requires coordinated policy alignment, cultural mindset shifts, and proactive stakeholder engagement
- Critical for realizing the full potential of risk-based clinical trial management

Global Inspectorate Alignment:

- PIC/S GCP Expert Circle develops training to harmonize inspection practices worldwide
- Ensures inspections are consistent and reflect ICH E6(R3)’s risk-based framework

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Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products

Anindita Saha

Associate Director for Data Science and Artificial Intelligence Policy (Acting), CDER

Associate Director for Strategic Initiatives, Digital Health Center of Excellence, CDRH

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AI Across the Drug Product Life Cycle

Discovery

- Drug Target Identification, Selection, and Prioritization
- Compound Screening and Design

Nonclinical Research

- PK/PD and toxicologic studies
- Dose range finding

Clinical Research

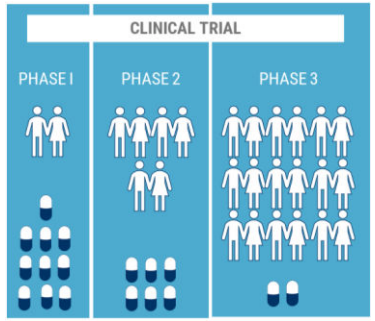


Image source: cbinsights.com

- Dose range finding
- Site selection
- Recruitment and Retention
- Adherence
- Data collection, management, and analysis
- RWD analyses
- Clinical endpoint assessment

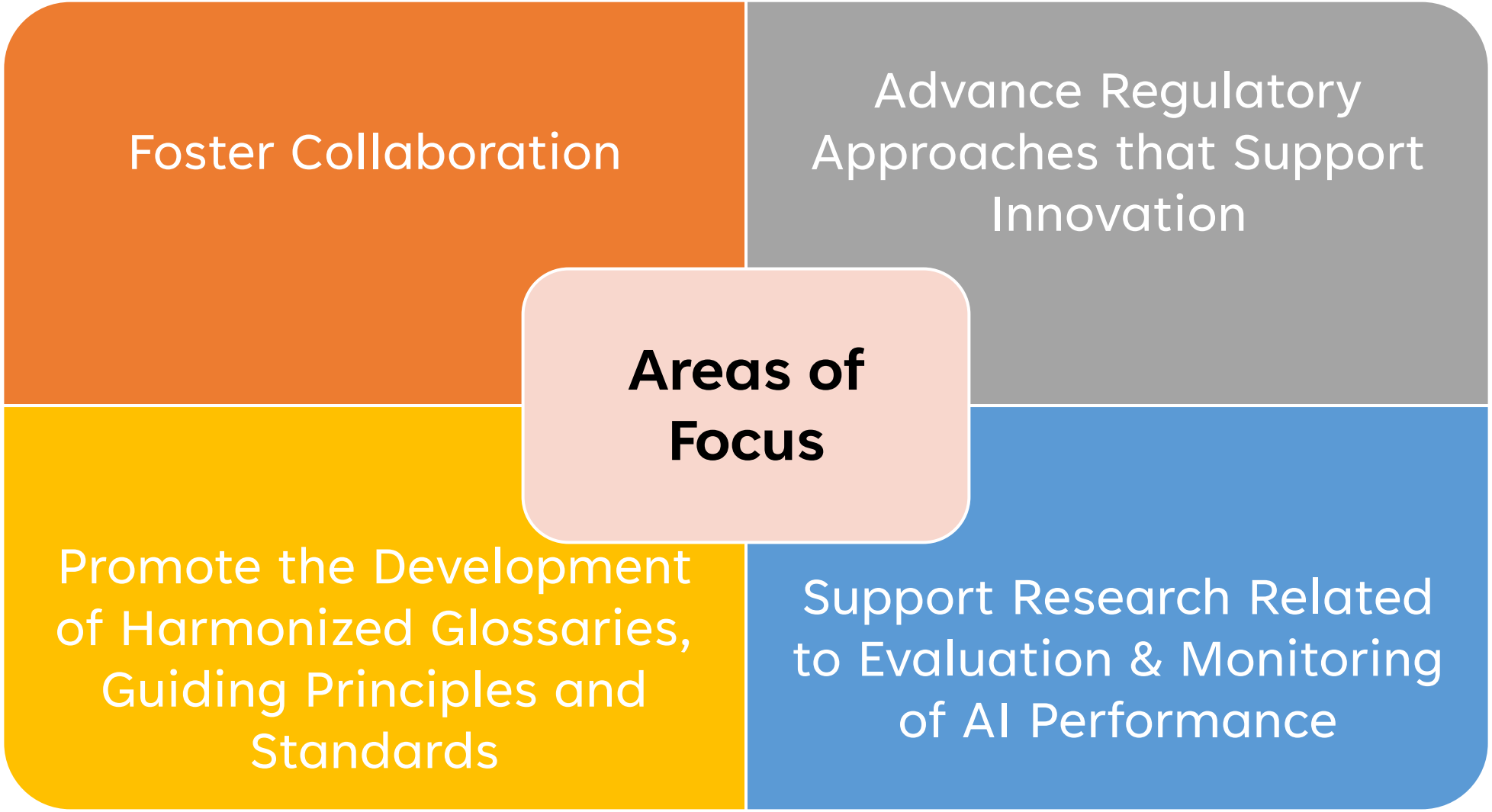
Manufacturing and Postmarket Safety Monitoring

- Advanced pharmaceutical manufacturing
- Post-market safety surveillance or pharmacovigilance (PV)

CDER's Core Principles for AI Use in Regulatory Decision Making

- **Adaptive Regulation:** Technology-enabling, responsive, iterative approach to accelerate adoption and maintain patient safety
- **Risk-Based Regulation:** Move from one-size-fits-all regulation of emerging technology to a data-driven, segmented approach commensurate with AI model risk
- **Collaborative Regulation:** Align regulation by engaging a broad set of players across the ecosystem (e.g., tech, biotech, pharma, patients, regulators, etc.)

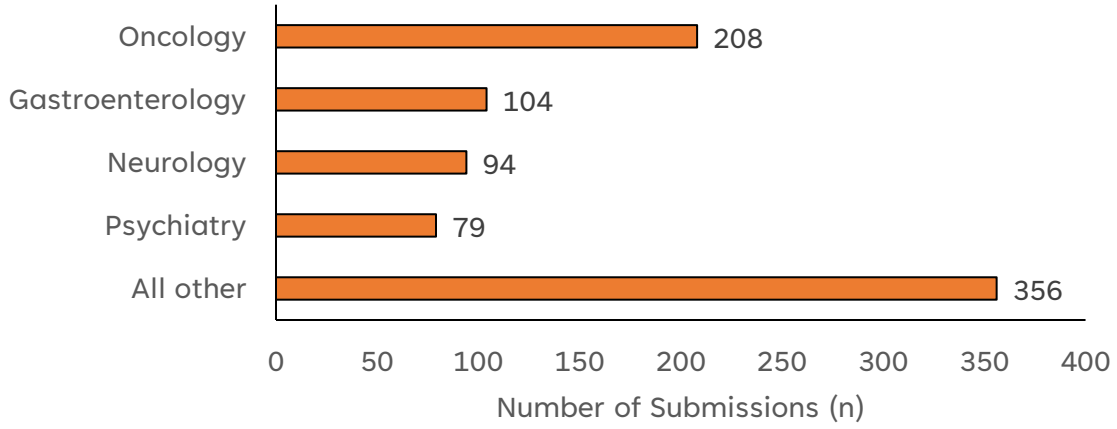
How do we move forward?



Source: Adapted from Artificial Intelligence and Medical Products https://www.fda.gov/media/177030/download

CDER has received >800 submissions with AI

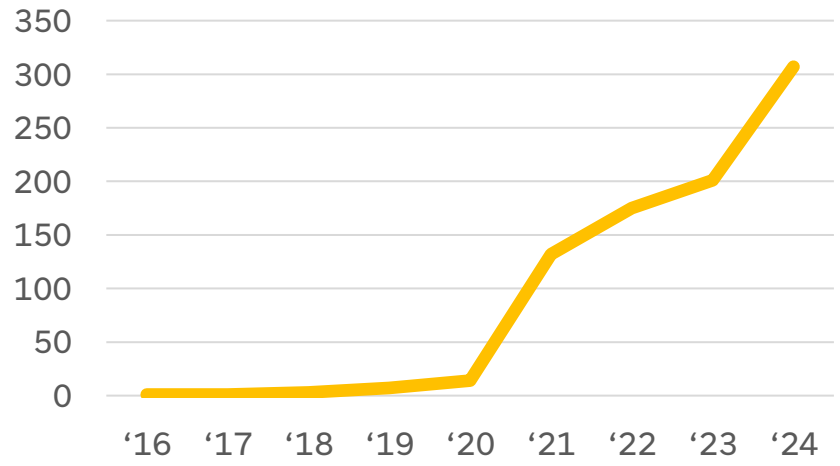
Submissions by Therapeutic Area



Example Use Cases of AI

- Patient selection
- Outcome prediction
- Confounding adjustment
- Pharmacometric modeling
- Digital Twins, external controls, synthetic controls
- Postmarket safety monitoring

Total Number of Submissions with AI by Year

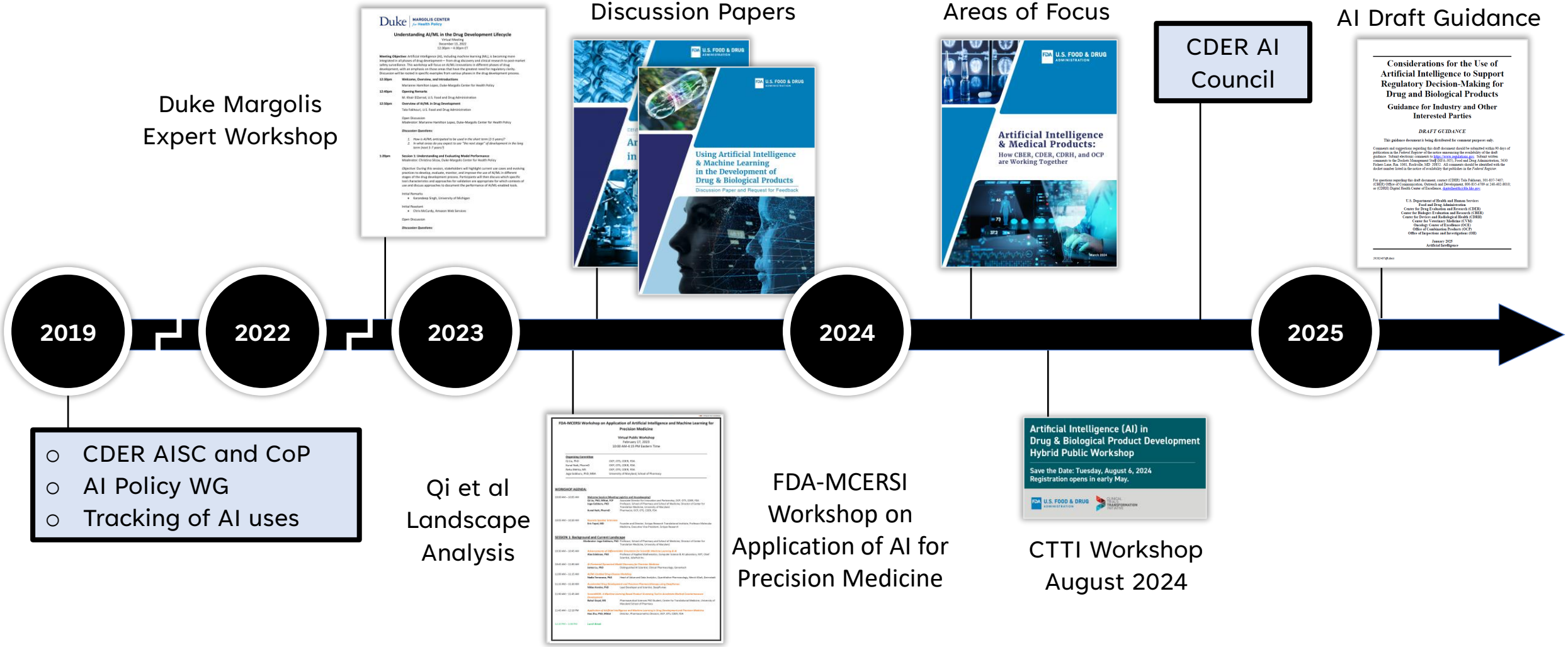


Submission	Year								
	'16	'17	'18	'19	'20	'21	'22	'23	'24
IND	-	-	2	6	12	128	153	174	248
NDA, ANDA, BLA	1	1	1	1	1	2	22	17	50
DDT, CPIM	-	-	-	-	1	2	-	10	9

Acknowledgement: Qi Liu, Menglun Wang

https://doi.org/10.1002/cpt.2668

Our Approach is Informed by Collaborative Engagement

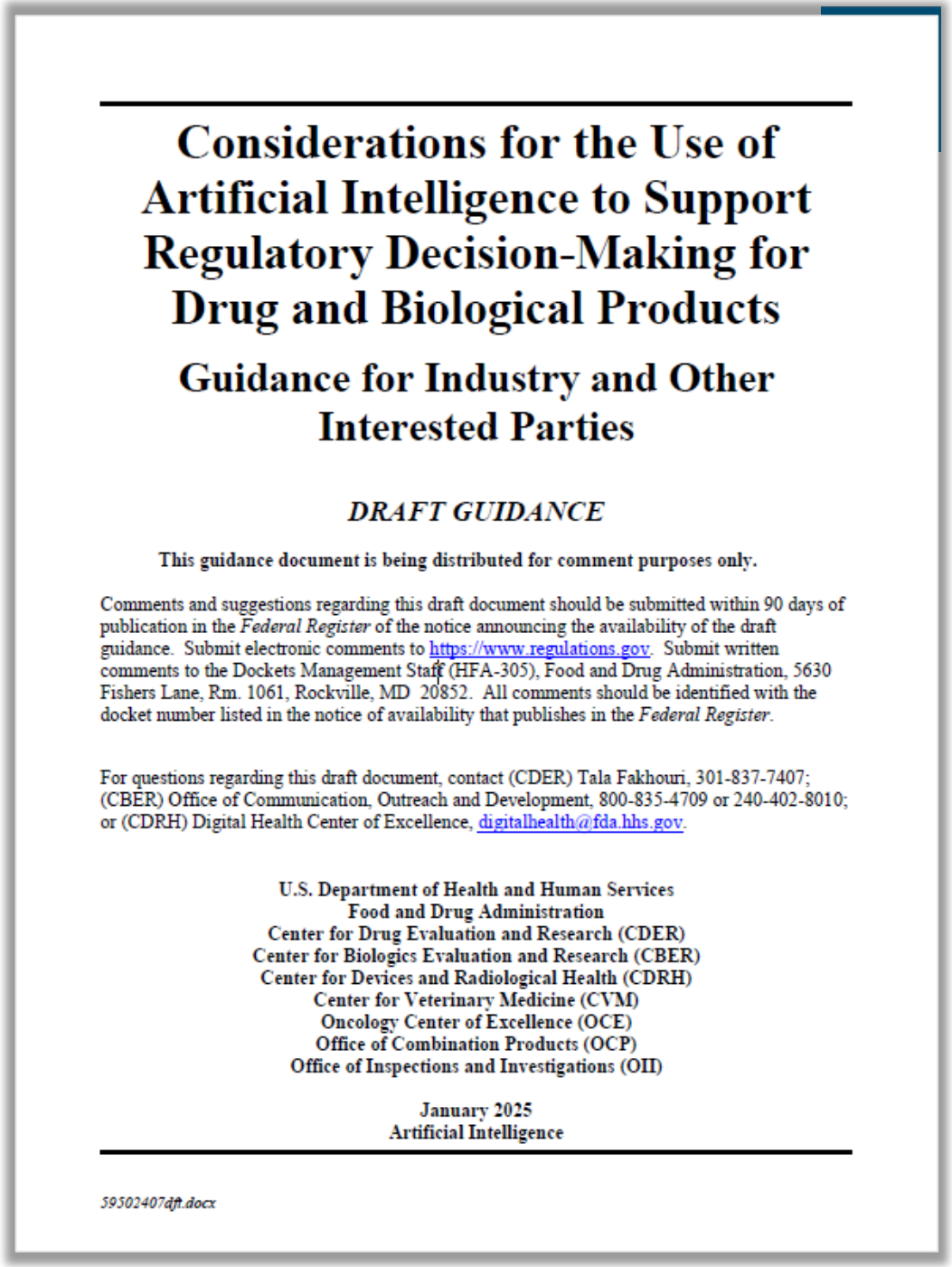


First AI Draft Guidance, Globally

Provides a **risk-based framework** to establish & evaluate the **credibility** of an AI model output for a particular **context of use (COU)**

Trust, established through the collection of evidence, in the performance of an AI model for a particular COU

The specific role & scope of the AI model to address a question of interest



Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products

Guidance for Industry and Other Interested Parties

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Tala Fakhouri, 301-837-7407; (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010; or (CDRH) Digital Health Center of Excellence, digitalhealth@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
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Center for Veterinary Medicine (CVM)
Oncology Center of Excellence (OCE)
Office of Combination Products (OCP)
Office of Inspections and Investigations (OII)

January 2025
Artificial Intelligence

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Why did we need to publish an AI guidance?

FDA Needs

- How do we determine if AI use is appropriate for a specific context of use? & how do we determine AI model risk?
- How do we evaluate outputs from AI?
- How do we determine and communicate what we need from industry in a regulatory submission?

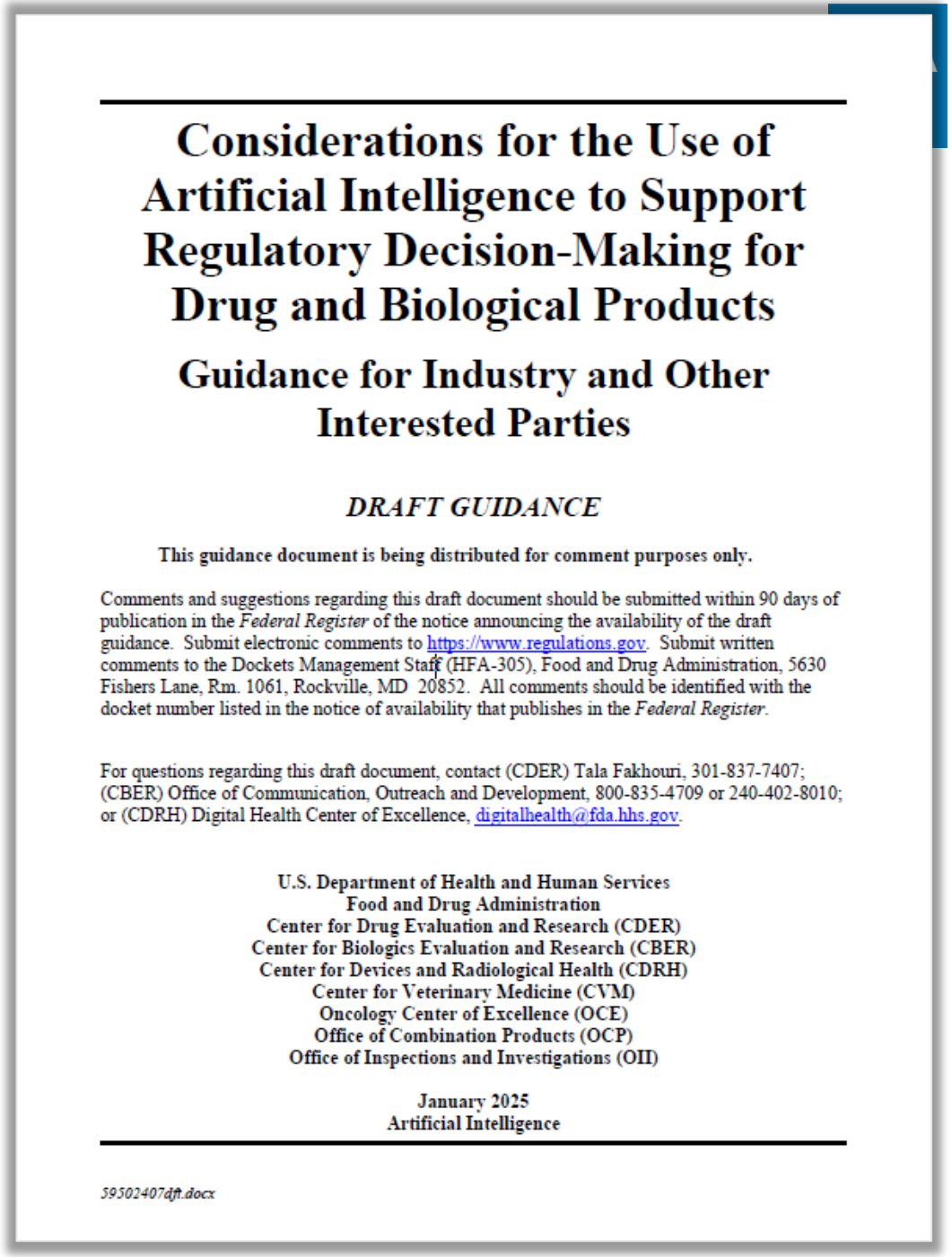
Industry* needs

- How will we know what is in or out of scope for FDA's oversight?
- How will we know that FDA will accept our AI use?
- How much information/data will the FDA require for AI use?
- How do we engage with the FDA on AI uses?

*Industry includes sponsors, technology and biotechnology companies, and other AI developers including academia

What's in the Guidance?

THE TABLE OF CONTENTS



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What's in the Guidance?

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- Definitions for:
  - AI
  - Machine learning
  - Credibility
  - Context of use (COU)

- Purpose of this guidance: providing a **risk-based** credibility assessment framework to establish the credibility of an AI model for a particular COU

What's in the Guidance?

THE TABLE OF CONTENTS

- In versus out of scope:
  - **In:** AI to produce information that supports regulatory decision-making for **safety**, **effectiveness**, or **quality** of drugs
  - **Out:** Drug discovery (generally) or operational efficiencies

- Framework intended to help industry plan, gather, organize, and document information to establish credibility of AI models for specific COUs

What's in the Guidance?

THE TABLE OF CONTENTS

I. Introduction

II. Scope

III. Background

IV. Considerations for AI use in the Drug Product Life Cycle

- A. A Risk-Based Credibility Assessment Framework
- B. Special Consideration: Life Cycle Maintenance of the Credibility of AI Model Outputs in Certain Contexts of Use
- C. Early Engagement

- Provides examples regarding AI uses to support regulatory decision-making, such as:
  - ✓ Reducing the number of animal-based PK, PD, and toxicological studies
  - ✓ Integrating multimodal data
  - ✓ RWD analyses, etc.

- Outlines unique challenges inherent to AI, including availability of fit for use data, interpretability & explainability, and data and model drift, etc..

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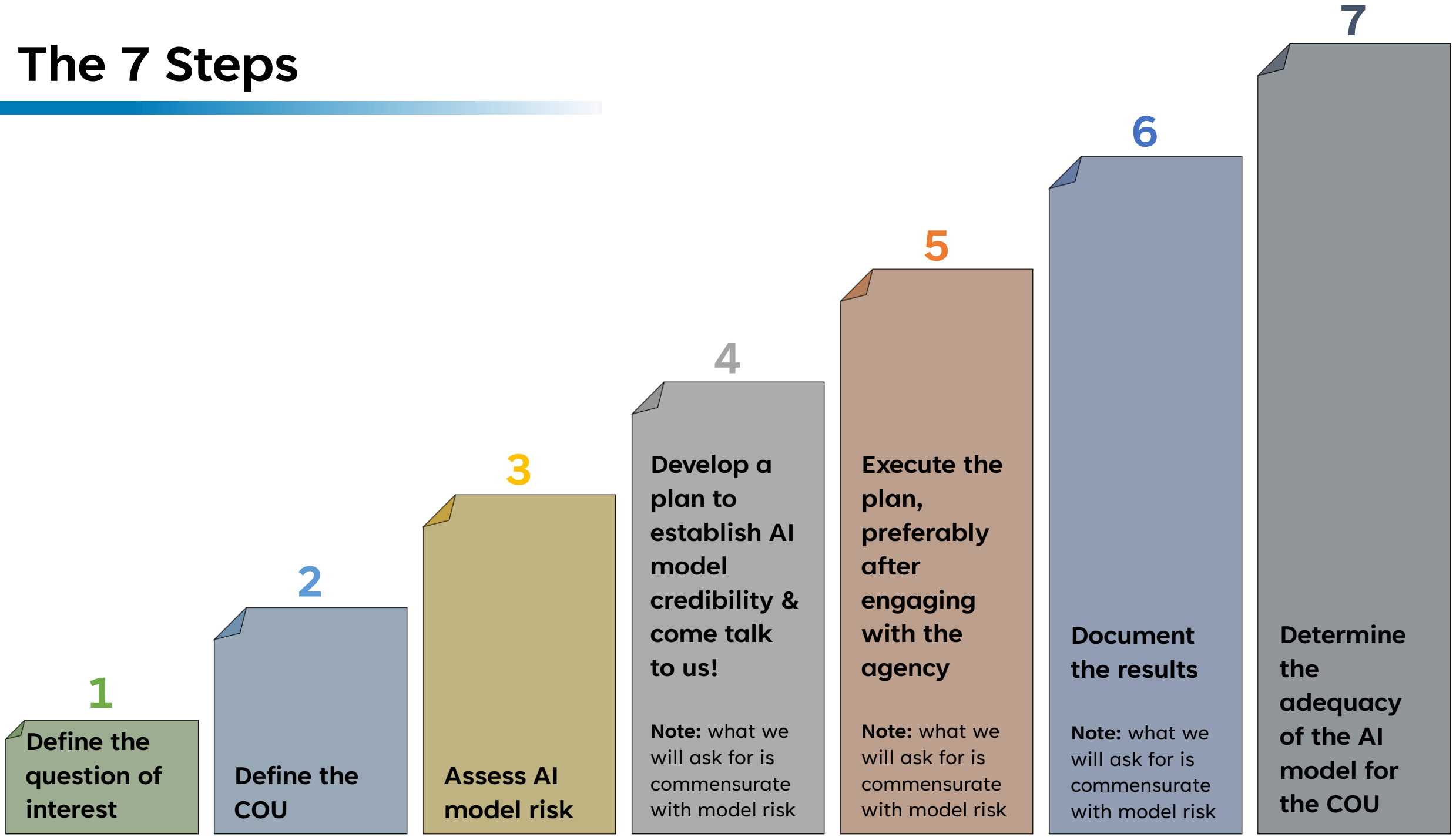
C. Early Engagement

- Framework is composed of **7 steps**
- The high-level concepts and principles based on an FDA-recognized consensus standard for computational models (not AI) in medical devices
- The technical aspects are consistent with a CDRH draft guidance on AI-enabled medical devices that was published on the same day

The 7 Steps


1
Define the question of interest
2
Define the COU
3
Assess AI model risk
4
Develop a plan to establish AI model credibility & come talk to us!
Note: what we will ask for is commensurate with model risk
5
Execute the plan, preferably after engaging with the agency
Note: what we will ask for is commensurate with model risk
6
Document the results
Note: what we will ask for is commensurate with model risk
7
Determine the adequacy of the AI model for the COU

The 7 Steps

Which participants can be considered low risk and do not need inpatient monitoring after dosing?

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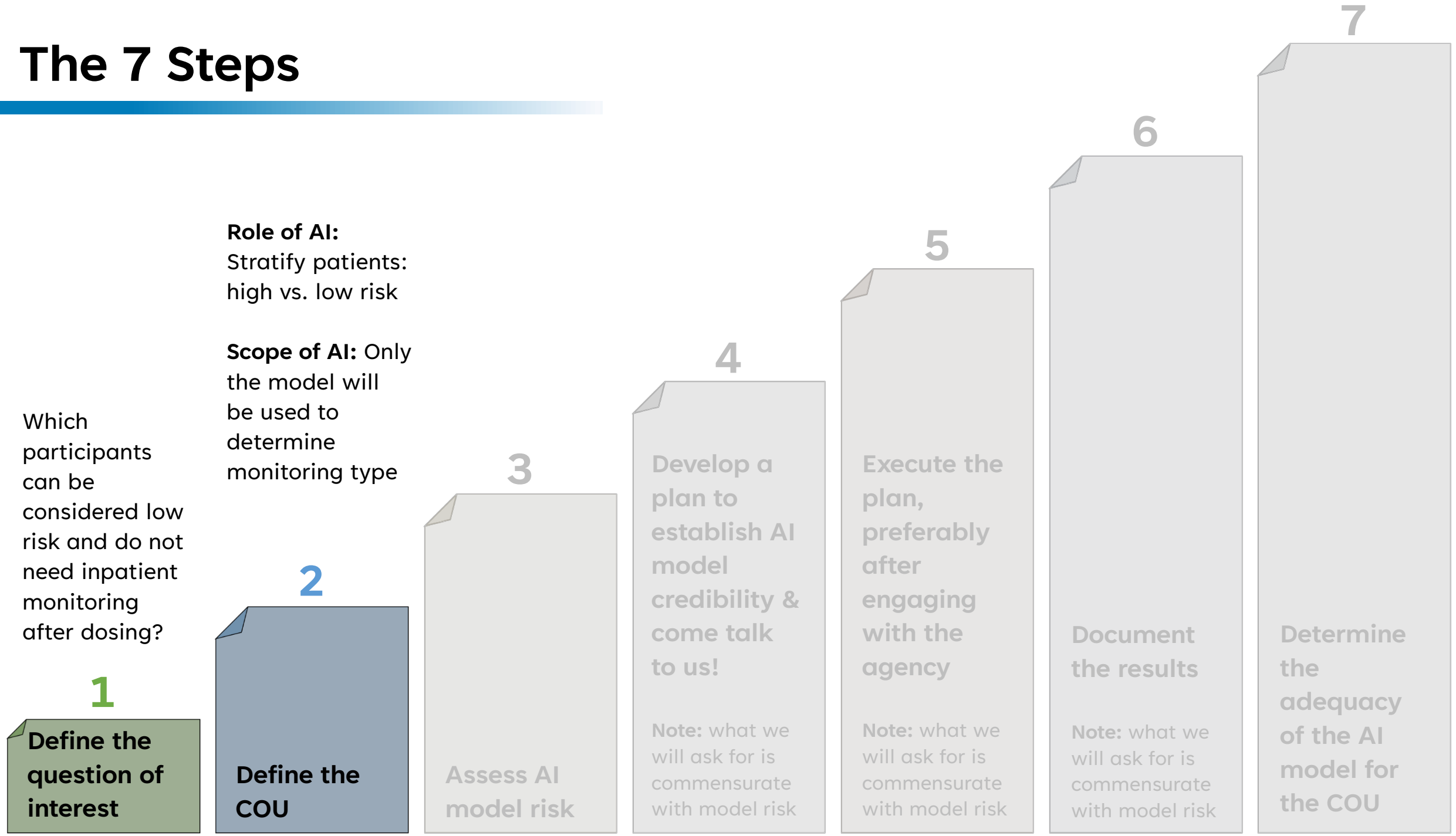
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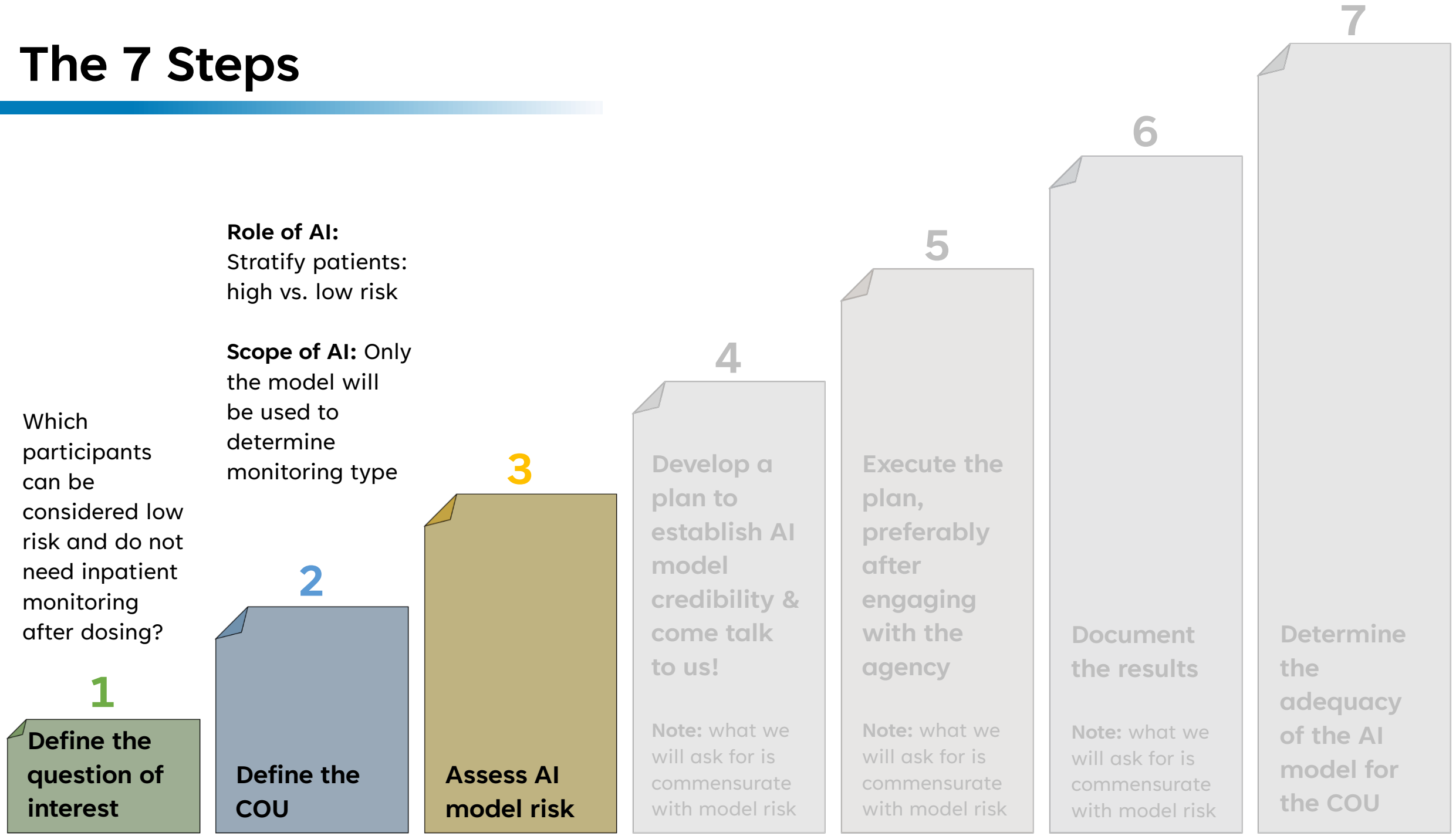
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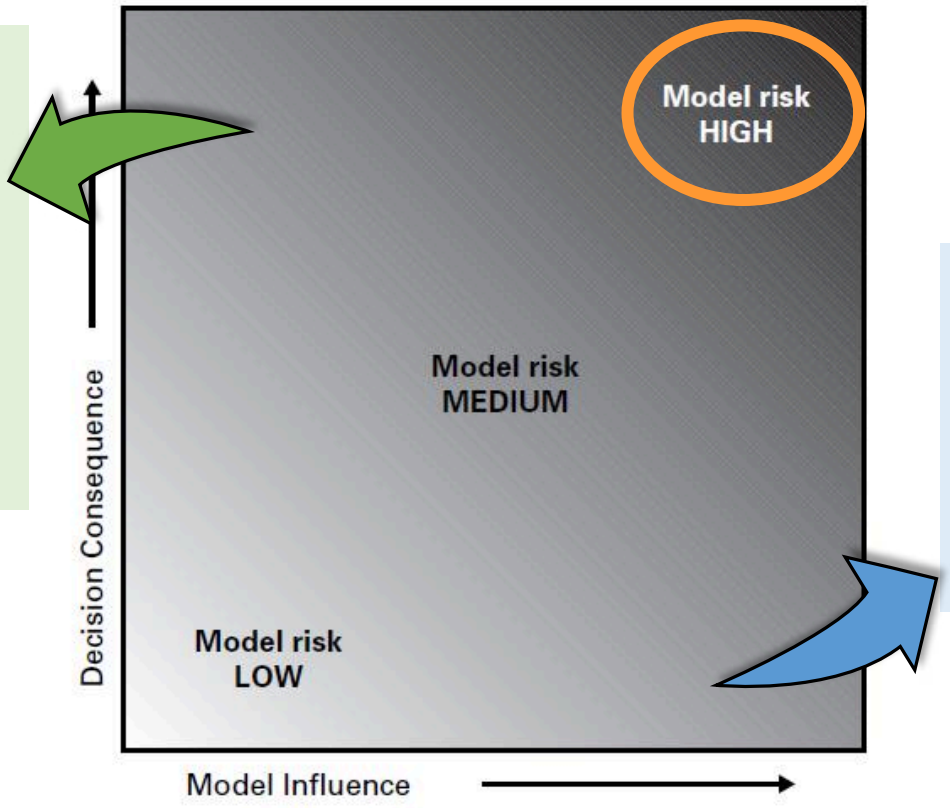
Step 3: How do we assess AI model risk?

Mischaracterization of patients' risk status could result in serious adverse reaction and potentially death

Decision Consequence: HIGH



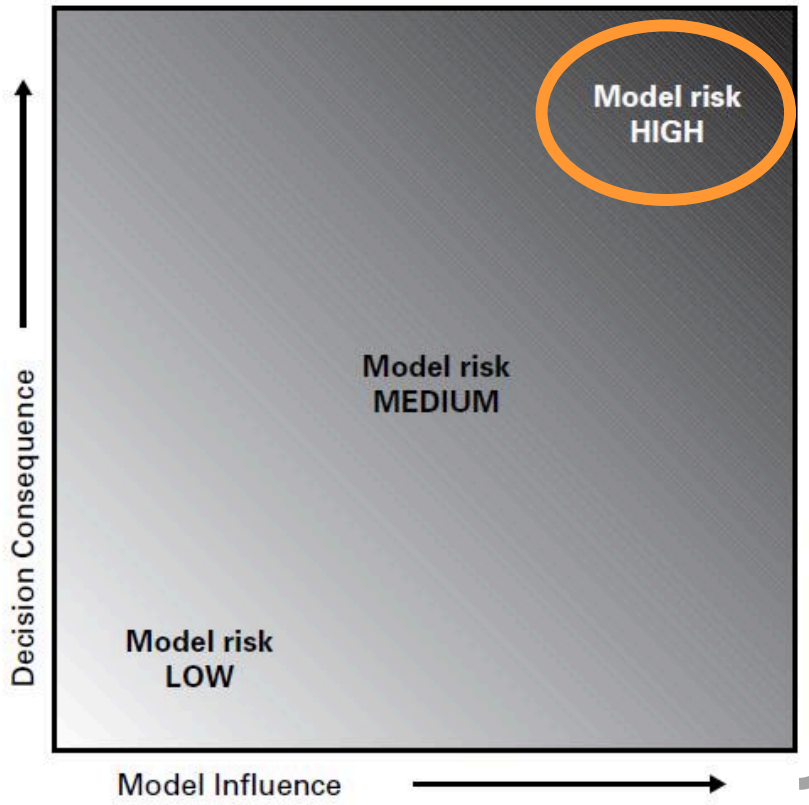
AI model is the ***only*** determinant of which type of monitoring a patient undergoes

Model Influence: HIGH

GENERAL NOTE: Darker shades indicate greater model risk.

Model risk matrix. The model risk transitions from low to high as decision consequence or model influence increases. The ratings for model influence and decision consequence are determined independently.

Step 3: How do we assess AI model risk?



GENERAL NOTE: Darker shades indicate greater model risk.

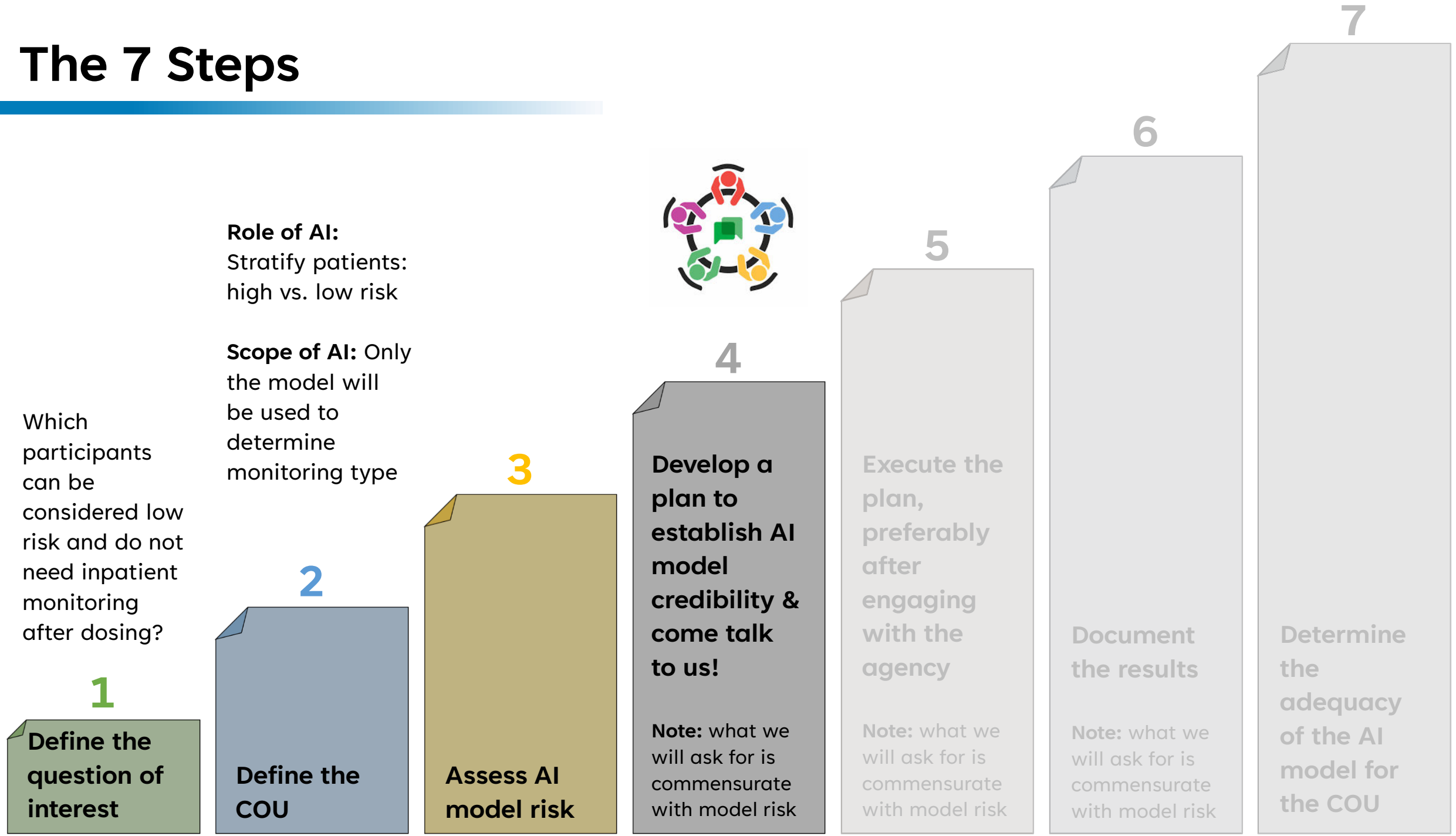
Activities used to establish AI model output credibility should be **commensurate with the model risk** & tailored to the COU

Examples of activities:

- Level of oversight
- Stringency of credibility assessments and performance acceptance criteria
- Risk mitigation strategy
- Type & extent of documentation & detail associated with AI use

Model risk matrix. The model risk transitions from low to high as decision consequence or model influence increases. The ratings for model influence and decision consequence are determined independently.

The 7 Steps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Step 4: Develop a plan to assess credibility

- Whether (if), when, and where the plan will be submitted to the FDA depends on how the sponsor engages with the Agency and on the COU
  - E.g., plan can be described in a formal meeting package or another appropriate engagement option

- Envisions interactive feedback even though the sponsor may not have detailed information at this point
  - But, at a minimum steps 1, 2, and 3 clearly articulated

- What we ask for in step 4 is consistent and aligned with a CDRH draft guidance on AI-enabled medical devices that was published on the same day

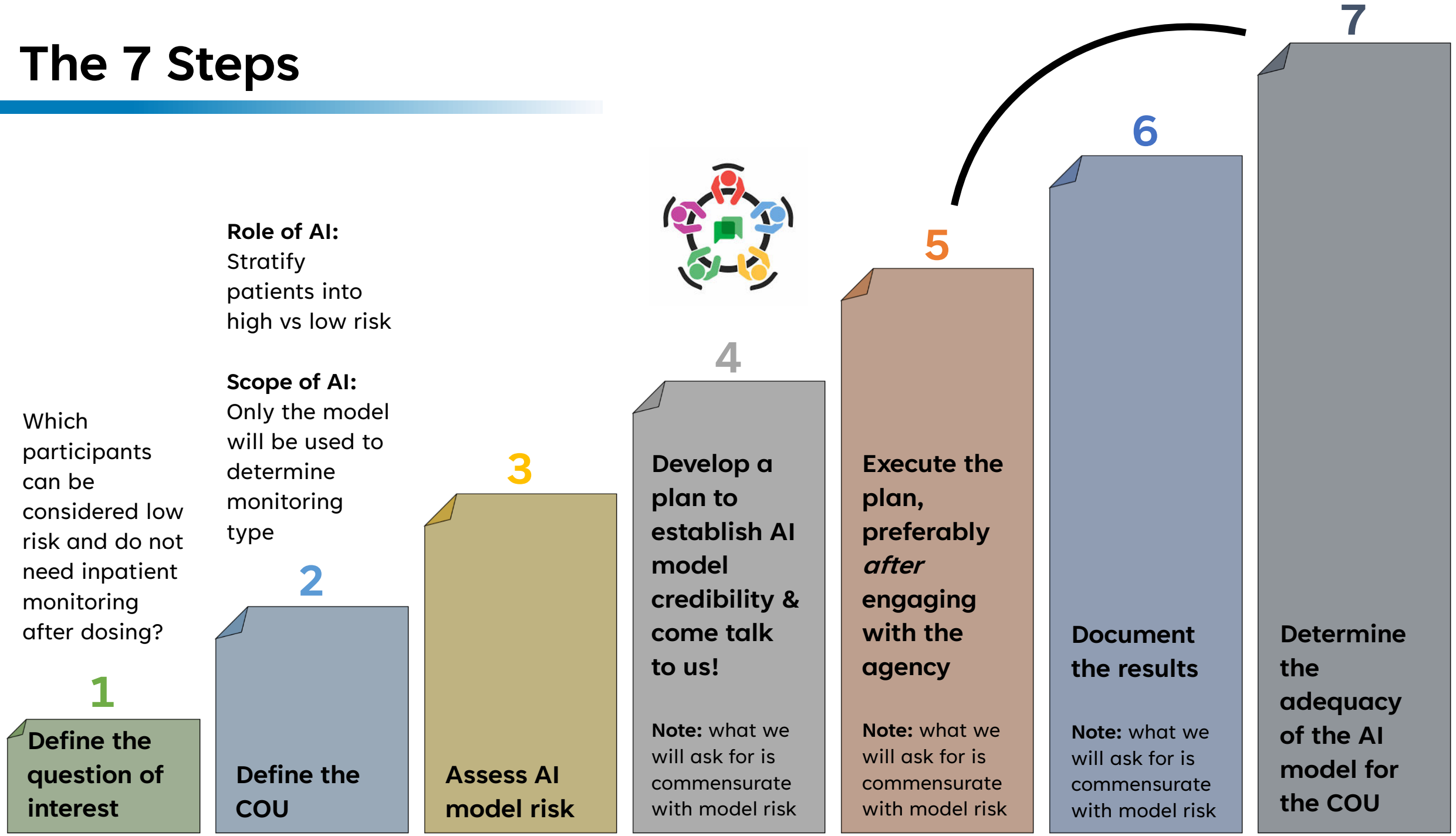
Step 4: Develop a plan to Assess Credibility

Some of what we ask for in step 4:

- **Describe the model and the model development process:**
  - What are the model inputs, outputs, architecture, features, parameters, rationale, etc.
  - What development data (training and tunning data) was used to develop the model, how was the data collected and processed, is it fit for the COU, etc.
  - How was the model trained, what performance metrics were used, was a pre-trained model used, describe calibrations, etc.

- **Describe the model evaluation process:**
  - Describe the evaluation of the fully trained model to assess its adequacy for the COU
  - What test data was used? Was it independent from the development data, was it applicable to the COU
  - What are the performance metrics used and what are the estimates

The 7 Steps


Which participants can be considered low risk and do not need inpatient monitoring after dosing?
1
Define the question of interest
Role of AI: Stratify patients into high vs low risk
Scope of AI: Only the model will be used to determine monitoring type
2
Define the COU
3
Assess AI model risk
4
Develop a plan to establish AI model credibility & come talk to us!
Note: what we will ask for is commensurate with model risk
5
Execute the plan, preferably *after* engaging with the agency
Note: what we will ask for is commensurate with model risk
6
Document the results
Note: what we will ask for is commensurate with model risk
7
Determine the adequacy of the AI model for the COU

What's in the Guidance?

THE TABLE OF CONTENTS

- Important in certain stages of the drug product lifecycle
- Management of changes to AI models to ensure the model remains fit for use
- A risk-based approach for life cycle maintenance may help sponsors assess the impact of a change or changes to the AI model performance

What's in the Guidance?

THE TABLE OF CONTENTS

I. Introduction

II. Scope

III. Background

IV. Considerations for AI use in the Drug Product Life Cycle

A. A Risk-Based Credibility Assessment Framework

B. Special Consideration: Life Cycle Maintenance of the Credibility of AI Model Outputs in Certain Contexts of Use

C. Early Engagement

- We strongly encourage sponsors and to engage early with FDA to set expectations regarding the appropriate credibility assessment activities for the proposed model based on model risk and COU
- Various options can be used to engage with the Agency

Encouraging Early Engagement Depending on COU

CDER/CBER have several pathways for engagement that depend on COU

Examples of Engagement Pathways

Nonclinical Research

Clinical Research

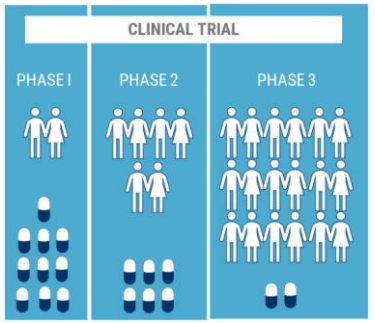


Image source: cbinsights.com

Manufacturing and Postmarket Safety Monitoring

Model-Informed Drug Development Program

Real-World Evidence (RWE) Program

Digital Health Technology (DHT) Program

Complex Innovative Trial Design Meeting Program

CDER Center for Clinical Trial Innovation (C3TI)

Emerging Drug Safety Technology Program (EDSTP)

CDER's Emerging Technology Program (ETP)

CBER's Advanced Technologies Team (CATT)

What's Next

- **Foster Collaboration:**
  - **At FDA:** collaborations between medical products centers on discussion papers, workshops, and guidance
  - **With other regulators:**
    - FDA and EMA bilateral engagements and sharing of mutual learnings
    - FDA & the Republic of Korea's Ministry of Food and Drug Safety "AI Regulatory & International Symposium on using AI for medical product development"
- **Promote the Development of Harmonized Glossaries, Guiding Principles and Standards**
  - **At FDA:** collaborations between medical products centers on glossaries (e.g., FDA DHT and AI Glossary)
  - **With other regulators:**
    - FDA and EMA bilateral engagements on guiding principles and glossaries
- **Advance Regulatory Approaches that Support Innovation**
  - Work to finalize AI guidance including analysis of comments on the guidance (>1,450 comments from 98 entities)

Thank you!

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SCDM Live

Regulatory Townhall

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Regulatory Townhall

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