

Envisioning Global Harmonization of MIDD: Opportunities and Challenges in the Implementation of the New ICH M15 MIDD Guidelines

Korea ICH Guideline Training 24th September 2025

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Overview

- **The ICH M15 Team**
- **The Journey**
- **Overview of the Draft Guideline**
- **Industry Perspective**
- **Questions**

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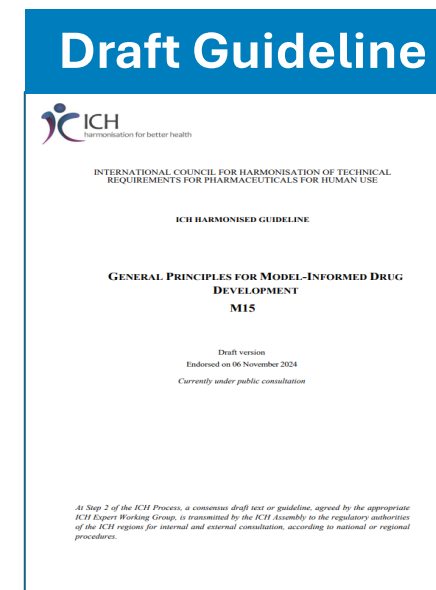
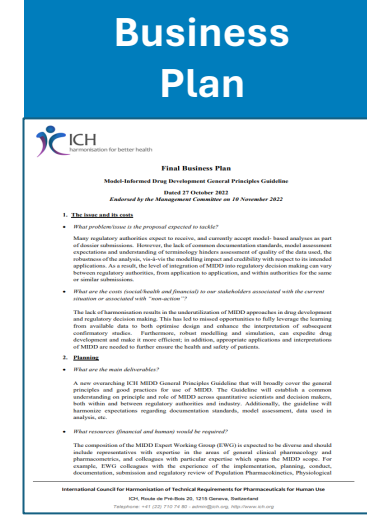
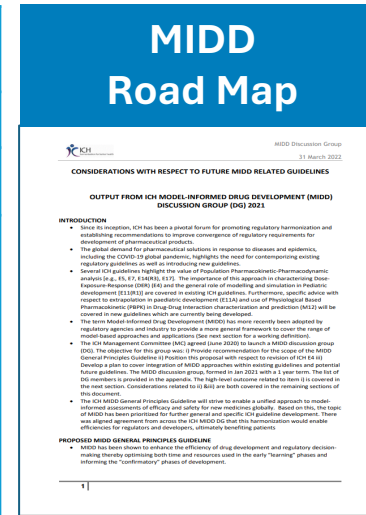
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The Journey to the draft guideline...

Dates	Deliverable
2019	<ul style="list-style-type: none"> Initial PhRMA Topic proposal
2020-2022	<ul style="list-style-type: none"> Road map , Concept paper
2022- 2024	<ul style="list-style-type: none"> ICH Step1 – Consensus Building >66 2-hr Team video meetings Three (4-5 day) F2F meetings >80 Core Team Planning Meetings Continuous offline discussions Two rounds of party review and a plenary review >1000 comments -> Regulatory Focus
November 2024	<ul style="list-style-type: none"> ICH Step 1 Technical document signed off by topic leaders & endorsed by ICH Assembly Step 2a -> Parties consensus on technical document Step 2b -> Draft Guideline adoption by Regulators (November 6th) Step 2 Summary Slides & Template
Q1-Q3 2025	<ul style="list-style-type: none"> Step 3 -> Regulatory Consultation & Discussion (including public consultation)
~End 2025	<ul style="list-style-type: none"> Step 3 -> Signoff Step 4 -> Adoption of M15 guideline
2026	<ul style="list-style-type: none"> Implementation of the Guideline

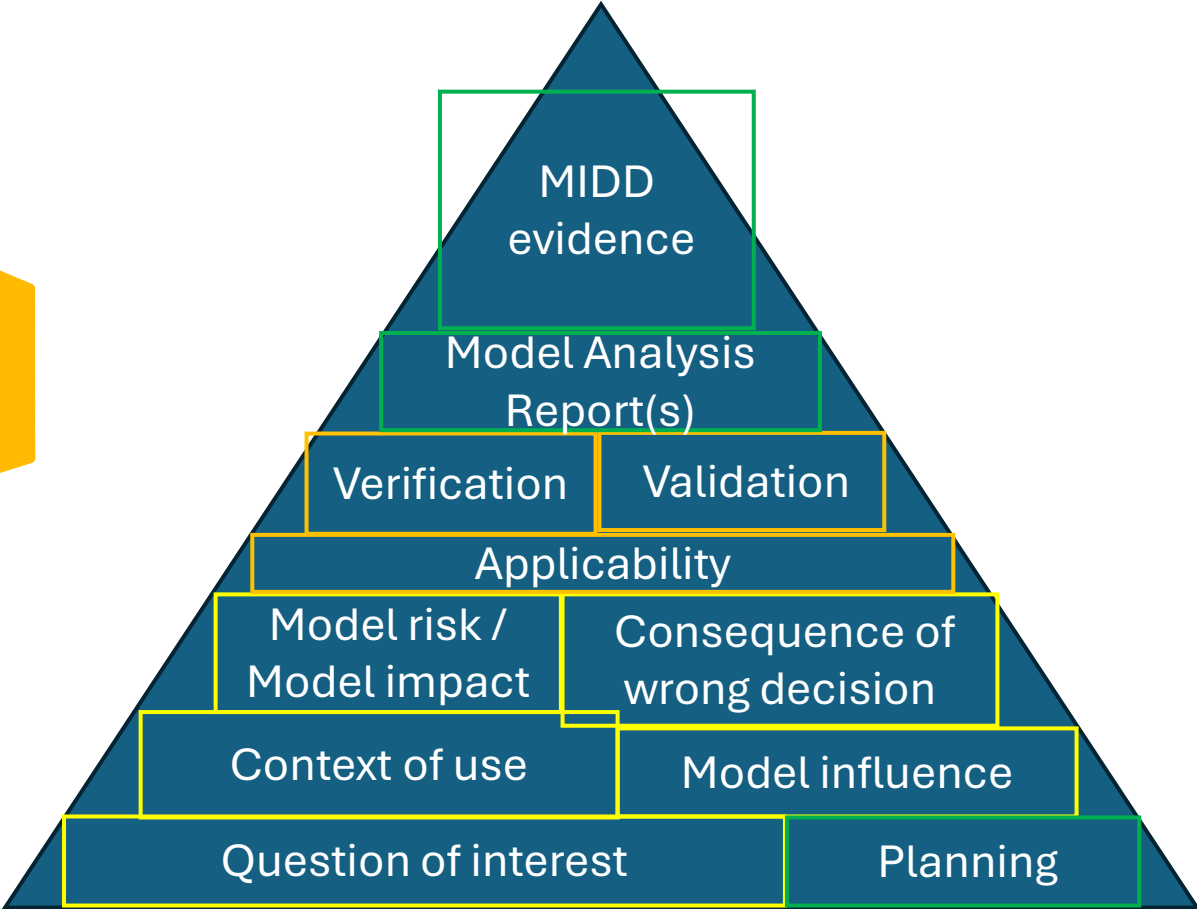
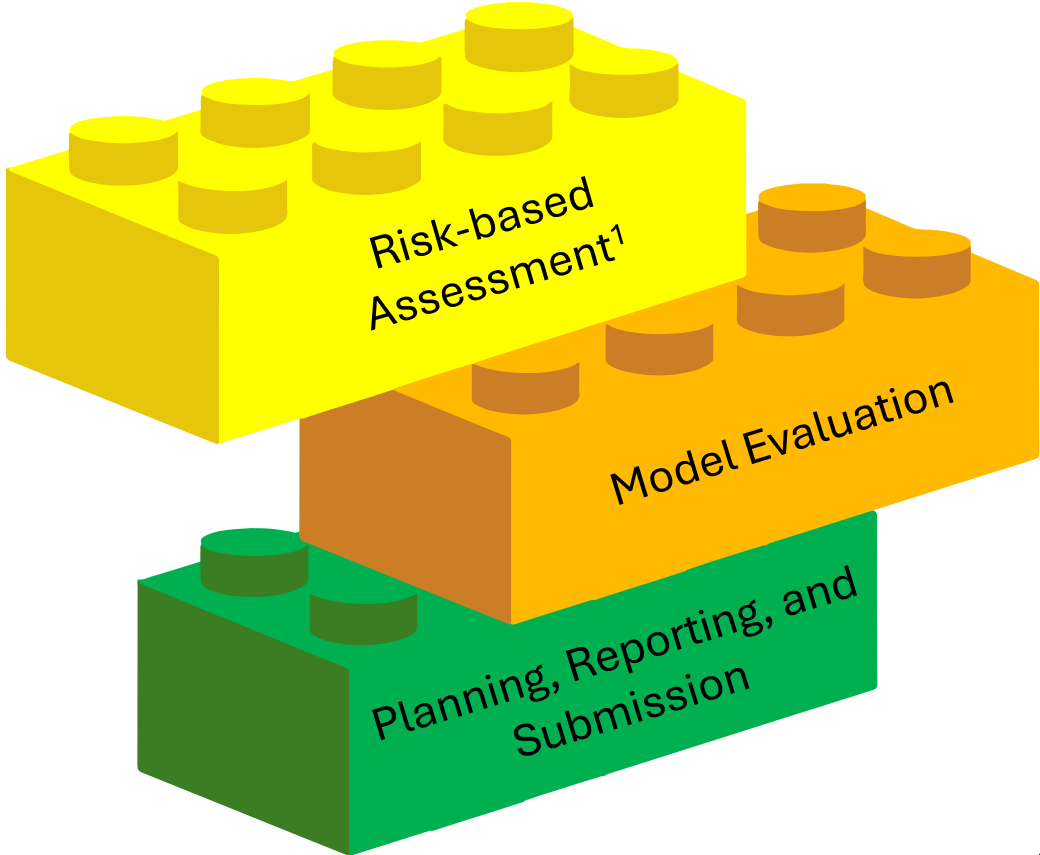


Guideline Objectives and Scope

Objectives

- **To provide general recommendations for planning, model evaluation, and documentation of MIDD evidence**
- **To establish a harmonized assessment framework (including associated terminology) for MIDD evidence**
- **To facilitate a multidisciplinary understanding of MIDD and associated evidence generation**

Three Core Concepts Provide the Building Blocks



¹Key source: ASME VVUQ 40- 2018 Assessing Credibility of Computational Modeling through Verification and Validation: Application to Medical Devices F .T. Musuamba White paper CPT:PSP 2021
C.Kuemmel Whitepaper CPT:PSP 2021

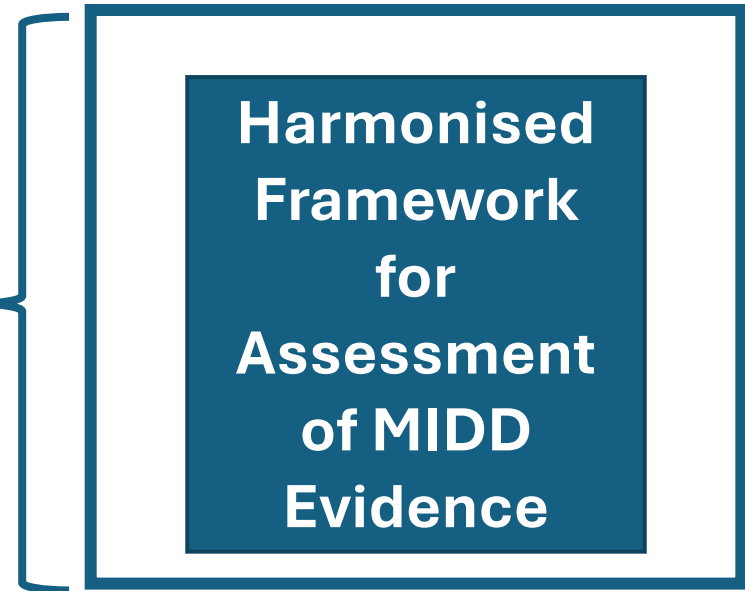
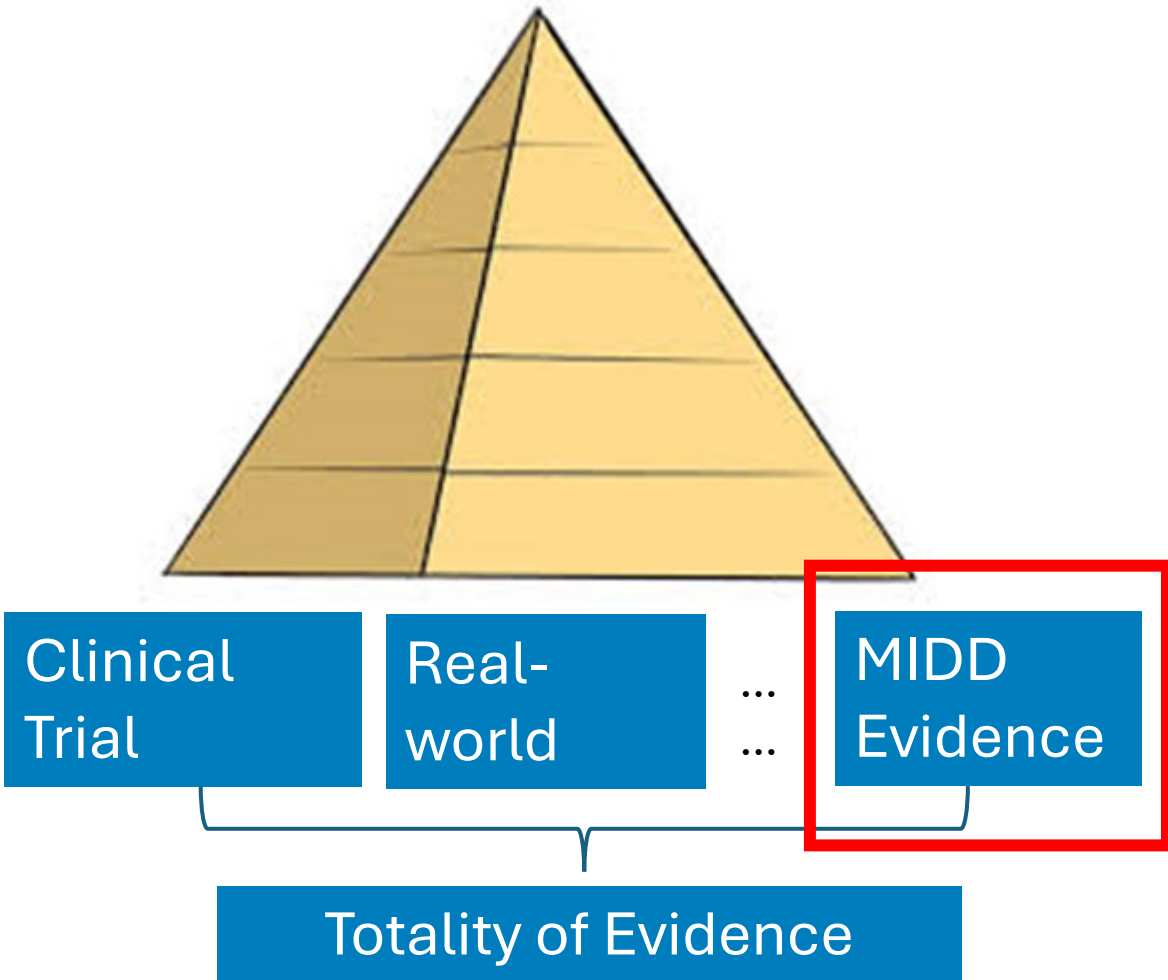
Adapted from ICH M15 ACOP2024 Presentation, Mark Peterson

MIDD Evidence for Regulatory Decision-Making



Regulatory Decision-Making

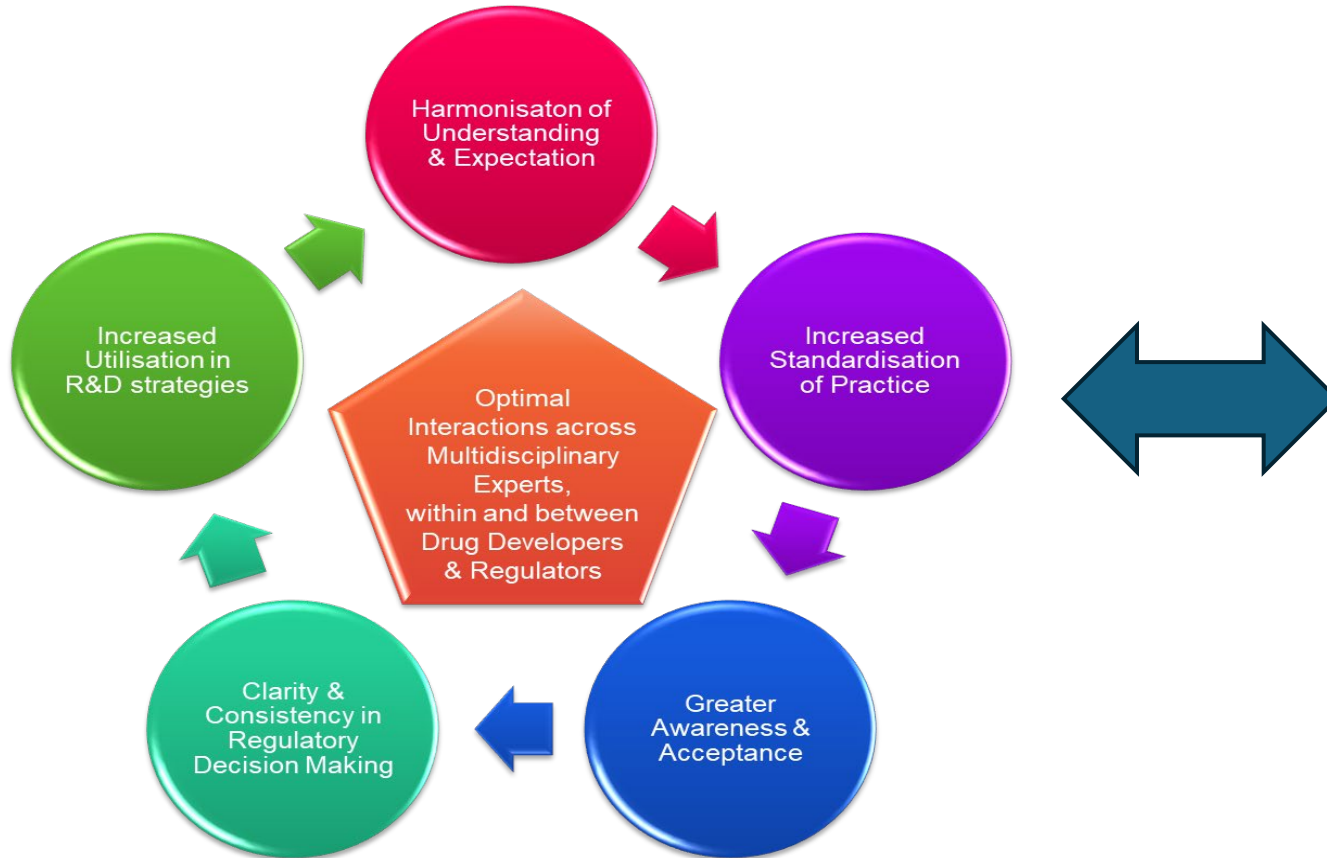
GENERAL PRINCIPLES FOR MODEL-INFORMED DRUG DEVELOPMENT
M15



Adapted from ICH M15 DIA2024 Presentation, Hao Zhu

Multidisciplinary Alignment is a Key Enabler

Global Harmonised Practice



Common Global Communication Tool:
Table for Assessment of MIDD Evidence

Item	Definition	Instruction	Entry
Key Assessment Elements			
Question of Interest¹	The question that MIDD is intended to answer.	State the Question of Interest.	
Context of Use	A description of the model(s) and its specific role and scope to answer the Question of Interest.	Provide a concise, clear, and explicit description of the model, the data used to build the model, the specific role of the model outcomes, and the other data or evidence that will contribute to the answer to the Question of Interest.	
Model Influence	The intended weight of the model outcomes in decision-making considering the contribution of other relevant information.	Describe the Model Influence; rate it as low, medium, or high considering other relevant information (e.g., nonclinical and clinical) to inform decision-making; and justify the rating.	
Consequence of Wrong Decision	The consequences (e.g., with respect to patient safety and/or efficacy) if a wrong decision is made, based on all available information.	Describe the consequence of a wrong decision; rate it as low, medium, or high based on the severity of the consequences a wrong decision may have on patient safety and efficacy; and justify the rating.	
Model Risk²	The contribution of the model outcomes to a possible wrong decision and subsequent potential undesirable consequences.	Describe the risk; rate it as low, medium, or high based on the Model Influence rate and the Consequence of a Wrong Decision rate; and justify the rating.	
Model Impact	The contribution of the model outcomes in relation to current regulatory expectations or standards in answering the Question of Interest.	Describe the impact; rate it as low, medium, or high considering current regulatory expectations or standards; and justify the rating.	
MIDD Planning Stage³			
The following items/rows are to be completed at the MIDD Planning Stage.			
Appropriateness	The rationale for why the proposed MIDD is suitable to answer the Question of Interest and covers the related key assumptions and required data.	Include a description and justification sufficient to facilitate regulatory interaction on the appropriateness of the proposed MIDD to answer the Question of Interest.	
Technical Criteria	A summary and rationale of the key criteria for Model Evaluation and model outcomes to establish the acceptability of the model (e.g., using an acceptance standard such as bioequivalence acceptance limits).	Include a description of the Technical Criteria for the assessment of Model Evaluation and model outcome. This should include sufficient details on the relevant metric(s).	
MIDD Evidence Submission Stage			
The following items/rows are to be filled at the MIDD Evidence Submission Stage after data collection and execution of the model.			
Model Evaluation	A brief discussion of the key results and conclusions of the technical evaluation ⁴ of the model.	Describe the key results and how they compare to and fulfill the Technical Criteria and conclude on the acceptability of the model performance and model outcome, with details being provided in the appropriate regulatory documentation (see Section 8).	
Outcome of the MIDD Evidence Assessment⁵	A concise summary of the multidisciplinary assessment of the MIDD evidence to answer the Question of Interest.	Provide a multidisciplinary integrative assessment and conclusion for the acceptability of the MIDD evidence to contribute to the answer to the Question of Interest, referring to the MIDD assessment framework elements.	
¹ If MIDD is planned to answer different Questions of Interest, it is recommended to use separate tables for each question. ² Model Risk should be interpreted in the context of answering a specific Question of Interest and is not to be perceived as a risk intrinsic to MIDD or M&E. ³ These items should also be provided at the MIDD Evidence Submission Stage. ⁴ Using the principles of Model Evaluation described in Section 3, with specific focus on Technical Criteria. ⁵ "Assessment" in this context does not refer to any regulatory review activities or processes.			

- Promote common terminology
- Encourage early alignment
- Enable common expectation

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Outline of the Guideline

Sequence of MIDD in Relation to the Relevant Guideline Sections

Stages	Planning and Regulatory Interaction		Implementation, Reporting, and Submission		
Sequence of Activities	Key Assessment Elements <ul style="list-style-type: none"> • Question of Interest • Context of Use • Model Influence • Consequence of Wrong Decision • Model Risk • Model Impact 	Additional Considerations for Interaction with Regulator and to Inform Decision-Making <ul style="list-style-type: none"> • Appropriateness of Proposed MIDD • Technical Criteria for model evaluation and model outcomes¹ <p>These should be documented (e.g., in a Model Analysis Plan [MAP]).</p>	Model Evaluation <ul style="list-style-type: none"> • Verification • Validation • Applicability assessment 	Model Analysis Reporting <ul style="list-style-type: none"> • Model Analysis Report(s) (MAR) 	Documentation for Regulatory Interactions and Submissions <ul style="list-style-type: none"> • Regulatory documents, including <ul style="list-style-type: none"> + Outcome of MIDD Evidence Assessment + References to all relevant MAPs and MARs
Relevant Guideline Section	Section 2.1 and Appendix 1	Sections 2.2 and 4.1 and Appendix 1	Section 3	Section 4.2 and Appendix 2	Sections 2 and 4.3 and Appendix 1

Inform Decision-Making

Note: Terms used in this table are defined in relevant guideline sections.

¹ Results derived from M&S (i.e., via model-based predictions or simulations) and associated conclusions that are typically aligned to a Question of Interest.

Table for Assessment of MIDD Evidence

Item	Definition	Instruction	Entry
Key Assessment Elements			
Question of Interest¹	The question that MIDD is intended to answer.	State the Question of Interest.	
Context of Use	A description of the model(s) and its specific role and scope to answer the Question of Interest.	Provide a concise, clear, and explicit description of the model, the data used to build the model, the specific role of the model outcomes, and the other data or evidence that will contribute to the answer to the Question of Interest.	
Model Influence	The intended weight of the model outcomes in decision-making considering the contribution of other relevant information.	Describe the Model Influence; rate it as low, medium, or high considering other relevant information (e.g., nonclinical and clinical) to inform decision-making; and justify the rating.	
Consequence of Wrong Decision	The consequences (e.g., with respect to patient safety and/or efficacy) if a wrong decision is made, based on all available information.	Describe the consequence of a wrong decision; rate it as low, medium, or high based on the severity of the consequences a wrong decision may have on patient safety and efficacy; and justify the rating.	
Model Risk²	The contribution of the model outcomes to a possible wrong decision and subsequent potential undesirable consequences.	Describe the risk; rate it as low, medium, or high based on the Model Influence rate and the Consequence of a Wrong Decision rate; and justify the rating.	
Model Impact	The contribution of the model outcomes in relation to current regulatory expectations or standards in answering the Question of Interest.	Describe the impact; rate it as low, medium, or high considering current regulatory expectations or standards; and justify the rating.	

¹ If MIDD is planned to answer different Questions of Interest, it is recommended to use separate tables for each question.

² Model Risk should be interpreted in the context of answering a specific Question of Interest and is not to be perceived as a risk intrinsic to MIDD or M&S.

Outline of the Guideline

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Stages	Planning and Regulatory Interaction		Implementation, Reporting, and Submission		
Sequence of Activities	Key Assessment Elements	Additional Considerations for Interaction with Regulator and to Inform Decision-Making	Model Evaluation	Model Analysis Reporting	Documentation for Regulatory Interactions and Submissions
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Table for Assessment of MIDD Evidence

Item	Definition	Instruction	Entry
MIDD Planning Stage³			
Appropriateness of Proposed MIDD	The rationale for why the proposed MIDD is suitable to answer the Question of Interest and cover the related key assumptions and required data.	Include a description and justification sufficient to facilitate regulatory interaction on the appropriateness of the proposed MIDD to answer the Question of Interest.	
Technical Criteria	A summary and rationale of the key criteria for Model Evaluation and model outcomes to establish the acceptability of the model (e.g., using an acceptance standard such as bioequivalence acceptance limits).	Include a description of the Technical Criteria for the assessment of Model Evaluation and model outcome. This should include sufficient details on the relevant metric(s).	
³ These items should also be provided at the MIDD Evidence Submission Stage. ⁴ Using the principles of Model Evaluation described in Section 3 of the draft guideline, with specific focus on Technical Criteria. ⁵ "Assessment" in this context does not refer to any regulatory review activities or processes.			

Outline of the Guideline

Sequence of MIDD in Relation to the Relevant Guideline Sections

Stages	Planning and Regulatory Interaction		Implementation, Reporting, and Submission		
Sequence of Activities	Key Assessment Elements <ul style="list-style-type: none"> • Question of Interest • Context of Use • Model Influence • Consequence of Wrong Decision • Model Risk • Model Impact 	Additional Considerations for Interaction with Regulator and to Inform Decision-Making <ul style="list-style-type: none"> • Appropriateness of Proposed MIDD • Technical Criteria for model evaluation and model outcomes¹ <p>These should be documented (e.g., in a Model Analysis Plan [MAP]).</p>	Model Evaluation <ul style="list-style-type: none"> • Verification • Validation • Applicability assessment 	Model Analysis Reporting <ul style="list-style-type: none"> • Model Analysis Report(s) (MAR) 	Documentation for Regulatory Interactions and Submissions <ul style="list-style-type: none"> • Regulatory documents, including <ul style="list-style-type: none"> + Outcome of MIDD Evidence Assessment + References to all relevant MAPs and MARs
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Inform Decision-Making

Note: Terms used in this table are defined in relevant guideline sections.
¹ Results derived from M&S (i.e., via model-based predictions or simulations) and associated conclusions that are typically aligned to a Question of Interest.

Model Evaluation

- **Elements**
 - **Verification:**

Ensuring user-generated codes are error-free, equations reflecting the model assumptions and their representation in the programming language or software are correct, and calculations are accurate
 - **Validation:**

Assessing the adequacy of the model robustness and performance.
Validation activities include assessing the relevance and appropriateness of the following:

 - the data, the model's conceptual form (i.e., overall structure and complexity),
 - the model assumptions, the approach to model development,
 - the graphical and numerical approaches to model performance and external validation.
 - **Applicability Assessment:**

Characterizing the relevance and adequacy of the data and model's contribution to answering the Question of Interest

MIDD Reporting and Submission

- **Provides recommendations on MAPs, MARs, and documentation (including the assessment table) with respect to regulatory interactions and submissions**
- **Model Analysis Plan (MAP)**
 - Pre-define and document each model analysis
 - Provision of MAPs during regulatory interactions can facilitate discussions.
- **Model Analysis Report (MAR)**
 - Document results of each model analysis submitted to regulators
 - Key model outcomes described in a single MAR or multiple MARs that support the answer to a Question of Interest should be summarized using the respective assessment table.

See guideline draft for additional details and an appendix outlining MAR content.

Summary of Guideline Content – Outline of the Guideline

Sequence of MIDD in Relation to the Relevant Guideline Sections

Stages	Planning and Regulatory Interaction		Implementation, Reporting, and Submission		
Sequence of Activities	Key Assessment Elements	Additional Considerations for Interaction with Regulator and to Inform Decision-Making	Model Evaluation	Model Analysis Reporting	Documentation for Regulatory Interactions and Submissions
	<ul style="list-style-type: none"> • Question of Interest • Context of Use • Model Influence • Consequence of Wrong Decision • Model Risk • Model Impact 	<ul style="list-style-type: none"> • Appropriateness of Proposed MIDD • Technical Criteria for model evaluation and model outcomes¹ <p>These should be documented (e.g., in a Model Analysis Plan [MAP]).</p>	<ul style="list-style-type: none"> • Verification • Validation • Applicability assessment 	<ul style="list-style-type: none"> • Model Analysis Report(s) (MAR) 	<ul style="list-style-type: none"> • Regulatory documents, including <ul style="list-style-type: none"> + Outcome of MIDD Evidence Assessment + References to all relevant MAPs and MARs
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Inform Decision-Making

Note: Terms used in this table are defined in relevant guideline sections.

¹ Results derived from M&S (i.e., via model-based predictions or simulations) and associated conclusions that are typically aligned to a Question of Interest.

Table for Assessment of MIDD Evidence

Item	Definition	Instruction	Entry
MIDD Evidence Submission Stage			
Model Evaluation	A brief discussion of the key results and conclusions of the technical evaluation ⁴ of the model.	Describe the key results and how they compare to and fulfill the Technical Criteria and conclude on the acceptability of the model performance and model outcome, with details being provided in the appropriate regulatory documentation.	
Outcome of the MIDD Evidence Assessment⁵	A concise summary of the multidisciplinary assessment of the MIDD evidence to answer the Question of Interest.	Provide a multidisciplinary integrative assessment and conclusion for the acceptability of the MIDD evidence to contribute to the answer to the Question of Interest, referring to the MIDD assessment framework elements.	
<p>³ These items should also be provided at the MIDD Evidence Submission Stage.</p> <p>⁴ Using the principles of Model Evaluation described in Section 3 of the draft guideline, with specific focus on Technical Criteria.</p> <p>⁵ "Assessment" in this context does not refer to any regulatory review activities or processes.</p>			

From Concept to Harmonized Framework: An Overview of the Draft ICH M15 Guideline on Model-Informed Drug Development

Industry Perspective

IFPMA Topic Leader:

Jiawei Wei, Novartis

Overview

- The ICH M15 Team
- The Journey
- Overview of the Draft Guideline
- **Industry Perspective**
- Questions

Key benefits of the M15 MIDD guidance from industry perspective

- Provides ICH-aligned language and process for documenting and evaluating MIDD analyses and associated evidence
- Facilitates multidisciplinary understanding of the requirements for MIDD when used to generate evidence
- Facilitates harmonized reporting of MIDD evidence across ICH global regulators in submissions
- An example is presented to illustrate the value of the guidance from industry perspective.

A Sponsor's scenario & use of M15 – for Illustrative purposes

- Use MIDD evidence to justify label change from weight-based to fixed dose for a monoclonal antibody previously approved to treat a life-threatening condition
- Phase I–III studies conducted using body weight-based dosing across a large weight range providing:
 - robust popPK (reviewed by health authorities with no concerns)
 - relationship between exposure and efficacy (% of responders)
 - identification of the exposure range where efficacy plateaus
 - characterization of dose-exposure-safety
 - a clear understanding of the between-subject variability
- Safety established across full exposure range (3 times higher than the registered dose)
- Additional real-world data with fixed dose is available, and clinical experience suggests fixed dosing would be more patient-centric

Key Assessment Elements

Question of Interest
Context of Use
Model Influence
Consequence of Wrong Decision
Model Risk
Model Impact

Definition	Instruction	Entry
The question that MIDD is intended to answer.	State the Question of Interest.	Could the approved body-weight-based dosing be replaced by a fixed dosing regimen while still providing a similar efficacy and safety profile?

Key Assessment Elements

Question of Interest	Definition	Instruction	Entry
Context of Use	A description of the model(s) and its specific role and scope to answer the Question of Interest.	Provide a concise, clear, and explicit description of the model, the data used to build the model, the specific role of the model outcomes, and the other data or evidence that will contribute to the answer to the Question of Interest.	<p>Strategy to address COU:</p> <ul style="list-style-type: none"> ▪ Previously developed PPK model will be simulated to identify fixed dose that generates exposure comparable to the approved body-weight-based dosing. <p>Additional Evidence:</p> <ul style="list-style-type: none"> ▪ Established dose-exposure relationship over wide body-weight-based dose range and in a large population. ▪ The approved body-weight-based dose: <ol style="list-style-type: none"> 1. was in the mid-range of the tested Phase II doses 2. generated exposure well at the plateau of the exposure-response curve ▪ A favorable safety profile was observed across all dose ranges tested in clinical trials, further confirmed by RWE.
Model Influence			
Consequence of Wrong Decision			
Model Risk			
Model Impact			

Key Assessment Elements

Question of Interest	Definition	Instruction	Entry
Context of Use	The intended weight of the model outcomes in decision-making considering the contribution of other relevant information.	Describe the Model Influence; rate it as low, medium, or high considering other relevant information (e.g., nonclinical and clinical) to inform decision-making; and justify the rating.	<ul style="list-style-type: none"> ▪ The model outcome is the sole factor identifying the fixed dose. ▪ Additional evidence (see previous slide) ensures the safety of the predicted fixed dose. ▪ Model Influence: High
Model Influence			
Consequence of Wrong Decision			
Model Risk			
Model Impact			

Key Assessment Elements

Question of Interest	Definition	Instruction	Entry
Context of Use	<p>The consequences (e.g., with respect to patient safety and/or efficacy) if a wrong decision is made, based on all available information.</p>	<p>Describe the consequence of a wrong decision; rate it as low, medium, or high based on the severity of the consequences a wrong decision may have on patient safety and efficacy; and justify the rating.</p>	<ul style="list-style-type: none"> ▪ Consequence of wrong decision on the severity of the disease is high as a wrong dose could have detrimental effects on efficacy and safety of the drug in this life-threatening disease. ▪ However <ul style="list-style-type: none"> ○ Favorable safety profile observed across all dose ranges tested in clinical trials, further confirmed by RWE. ○ Significant deviation of predicted fixed dose (i.e., significantly higher or lower exposure) from the approved weight-based dose is expected to remain within a safe and efficacious range. ○ The likelihood of a wrong decision leading to patient harm in terms of efficacy and safety is low. ▪ Consequence of Wrong Decision: Low
Model Influence			
<p>Consequence of Wrong Decision</p>			
Model Risk			
Model Impact			

Key Assessment Elements

Question of Interest
Context of Use
Model Influence
Consequence of Wrong Decision
Model Risk
Model Impact

Definition	Instruction	Entry
The contribution of the model outcomes to a possible wrong decision and subsequent potential undesirable consequences.	Describe the risk; rate it as low, medium, or high based on the Model Influence rate and the Consequence of a Wrong Decision rate; and justify the rating.	<ul style="list-style-type: none"> The model outcome is the sole factor identifying the fixed dose despite high severity of the disease. Significant deviations from the predicted fixed-dose exposure are expected to remain within a safe and effective range, reducing the likelihood of harm. The model's outcomes carry a low potential for undesirable consequences. Model Risk: Medium

Key Assessment Elements

Question of Interest
Context of Use
Model Influence
Consequence of Wrong Decision
Model Risk
Model Impact

Definition	Instruction	Entry
The contribution of the model outcomes in relation to current regulatory expectations or standards in answering the Question of Interest.	Describe the impact; rate it as low, medium, or high considering current regulatory expectations or standards; and justify the rating.	<ul style="list-style-type: none"> ▪ A change from weight-based dosing to a fixed dose in a drug label would typically require, at a minimum, a PK bridging study in healthy volunteers. ▪ The outcomes of the model are the sole factor identifying the fixed dose, thereby replacing clinical trials. ▪ Model Impact: High

MIDD Planning stage

Appropriateness of Proposed MIDD
Technical Criteria
Model Evaluation
Outcome of the MIDD Evidence Assessment

Definition	Instruction	Entry
<p>The rationale for why the proposed MIDD is suitable to answer the Question of Interest and cover the related key assumptions and required data.</p>	<p>Include a description and justification sufficient to facilitate regulatory interaction on the appropriateness of the proposed MIDD to answer the Question of Interest.</p>	<p>Rationale</p> <ul style="list-style-type: none"> • PPK model well validated with body weight effect • Dose-exposure-safety, efficacy relationships • Safety data + RWE <p>Key Assumptions</p> <ul style="list-style-type: none"> • Model captures body weight effect accurately • Fixed dose generated exposure limits are safe and efficacious <p>Key Data</p> <ul style="list-style-type: none"> • All available data and RWE; no additional data needed

MIDD Planning stage

Appropriateness of Proposed MIDD
Technical Criteria
Model Evaluation
Outcome of the MIDD Evidence Assessment

Definition	Instruction	Entry
A summary and rationale of the key criteria for Model Evaluation and model outcomes to establish the acceptability of the model (e.g., using an acceptance standard such as bioequivalence acceptance limits).	Include a description of the Technical Criteria for the assessment of Model Evaluation and model outcome. This should include sufficient details on the relevant metric(s).	<p>Refer to MAP for details</p> <p>M&S best practices:</p> <ul style="list-style-type: none"> • VPC's • Covariates representation • Model uncertainty captured <p>Comparability of exposure between fixed and mg/kg dose</p> <ul style="list-style-type: none"> • Dispersion: 5th & 95th percentile difference < X% • 90% CI of mean

MIDD Evidence Submission Stage

Appropriateness of Proposed MIDD
Technical Criteria
Model Evaluation
Outcome of the MIDD Evidence Assessment

Definition	Instruction	Entry
A brief discussion of the key results and conclusions of the technical evaluation of the model.	Describe the key results and how they compare to and fulfill the Technical Criteria and conclude on the acceptability of the model performance and model outcome, with details being provided in the appropriate regulatory documentation.	<p>Model meets all Technical Criteria, acceptable performance; refer to MAR for details</p> <p>PPK best practices:</p> <ul style="list-style-type: none"> • VPC criteria • Representation of covariates • Model uncertainty captured <p>Comparability of exposure between fixed and mg/kg dose</p> <ul style="list-style-type: none"> • Dispersion: 5th & 95th percentile difference < X% • 90% CI of mean

*The following items/rows are to be filled at the MIDD Evidence Submission Stage after data collection and execution of the model.

MIDD Evidence Submission Stage

Appropriateness of Proposed MIDD	Definition	Instruction	Entry
Technical Criteria	<p>A concise summary of the multidisciplinary assessment of the MIDD evidence to answer the Question of Interest.</p>	<p>Provide a multidisciplinary integrative assessment and conclusion for the acceptability of the MIDD evidence to contribute to the answer to the Question of Interest, referring to the MIDD assessment framework elements.</p>	<p>The proposed fixed dosing regimen, supported by robust simulations and comprehensive clinical data, is likely to maintain the desired efficacy and safety profile, supporting its potential implementation.</p> <p>Therefore, the MIDD evidence as assessed supports a fixed dose of X mg for weight range of Y to Z.</p>
Model Evaluation			
Outcome of the MIDD Evidence Assessment			

**The following items/rows are to be filled at the MIDD Evidence Submission Stage after data collection and execution of the model.*

In Conclusion,

This example illustrated the use of the assessment table as a valuable tool for communication to increase transparency and enable early alignment to facilitate subsequent acceptance of MIDD evidence

- within and between drug developers and regulatory authorities
- across multidisciplinary teams

Conclusions

- Drug development is a sequential and iterative process where MIDD can play an important strategic role.
- The guidance on assessment of MIDD evidence, model evaluation, and MIDD reporting and submission provided in this guideline is intended to facilitate the use of MIDD evidence to inform decision-making.
- The assessment table provides a tool for communication within and between drug developers and regulatory authorities across multidisciplinary teams to increase transparency and enable early alignment to facilitate subsequent acceptance of MIDD evidence.
- Additional training materials will be developed to complement this guideline.