Supporting ICH M15 Principles Through a Platform for Good Simulation Practices

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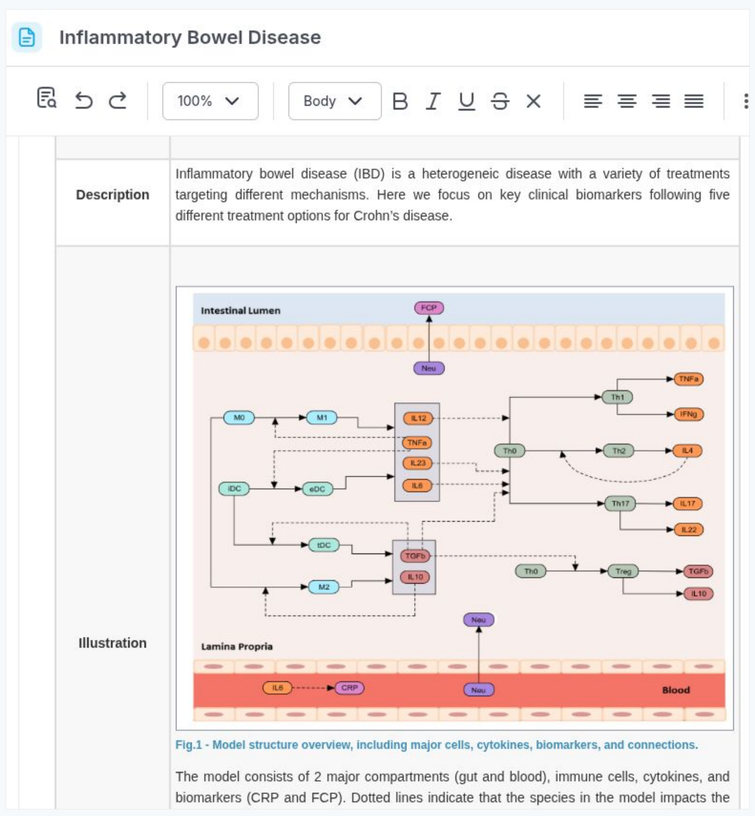
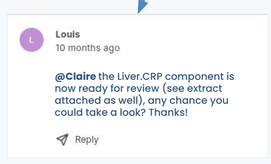
Drive **regulatory-ready M&S projects** with a secure, collaborative platform built for **traceability and transparency**

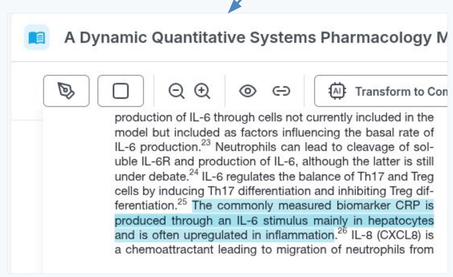
Jinkō[1], an M&S platform that enables confident interactions for multi-disciplinary teams

Clear, transparent documentation ⟷ Accessible equations, linked to knowledge ⟷ Traceable versioned assets, from kickoff to simulations

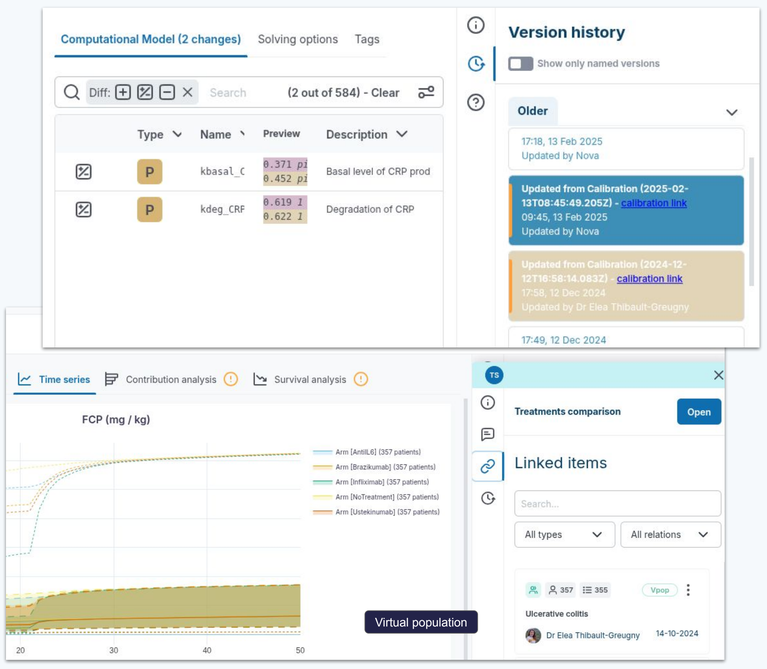




Pinpointed content from assets can be commented on, discussion threads are archived for traceability.



Specific section of interest from the scientific literature and data sources can be selected and used in various context in a project, here for instance to link the knowledge behind this particular model component.



Related items are interlinked automatically for ease of navigation / traceability between key assets. Here for instance we can see the virtual population the results are tied to.

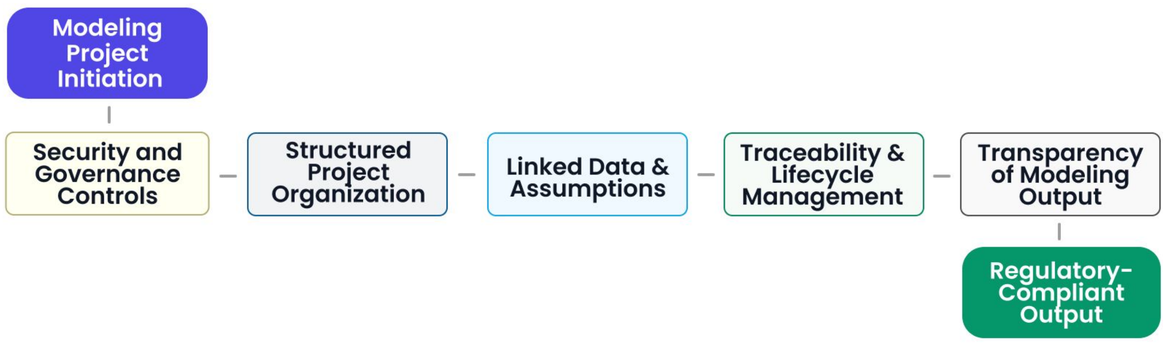
Fig. 1: Illustration of key elements in the jinkō platform allowing for the support of ICH M15 recommendations. The features illustrated are interconnected, built for accessibility and transparency for all M&S projects.

BACKGROUND

The ICH (International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use) aims at harmonizing the regulatory expectations in regions around the world, working with key Bodies such as the FDA and the EC. To this effect, the organization published in November 2024 a Draft Guidance documentation 'M15: General Principles for Model Informed Development[2], with key recommendations.

A Modeling & Simulation platform designed to support these recommendations must inherently incorporate robust security, interdisciplinary collaboration, transparency, traceability, and auditability across all its modules.

METHODS



Role-based access, secure authentication and alignment with regulatory standards (such as GDPR, HIPAA and ISO/IEC 27001), coupled with a clear hierarchized project organisation, automatic interlinking of assets and versioning, ensure that modeling workflows are implemented in a compliant and auditable manner. Intuitive interfaces further promote universal access of assets even for non-modelers.

RESULTS

Regular exchanges and edition are secured, pinpointed and transparent throughout the life-cycle of a project, for both internal and external stakeholders. A greater interactivity with key elements (models, results, assumptions, data..) allows for thorough reviews and traceability.

Early interactions with Regulatory Agencies are facilitated

Users are encouraged, notably via a documentation module and assets linking features, to follow the ICH M15 framework for Key Assessments Elements (and MIDD planning stage), thus enabling early interactions and review with Regulatories Agencies. The generation of of the Model Analysis Plan (MAP) and Model Analysis Reports (MAR) are also facilitated.

Model evaluation and auditability are by design

Model verification and validation activities are facilitated by an accessible model interface that clearly shows the model structure, equations used and link to knowledge. Model applicability is also easily assessed via fast calibration, real-life data overlay, simulations and traceable results.

CONCLUSION

- ➔ We illustrate here how a collaborative platform with traceability and transparency at its core can support R&D teams in leading M&S projects that follow Good Simulation Practices, in particular tied to the ICH M15 early recommandations.
- ➔ This 'white-box' approach is a foundation that paves the way to further the structural readiness of M&S projects for Regulatory audit and acceptance. It is already in line with the first ICH M15 Draft Guidance document and ready to adapt as it evolves.

REFERENCES

[1] https://www.jinko.ai
[2] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/m15-general-principles-model-informed-drug-development