Certara IQ: Intelligent QSP

Regulatory-grade QSP on every program, from plan to report

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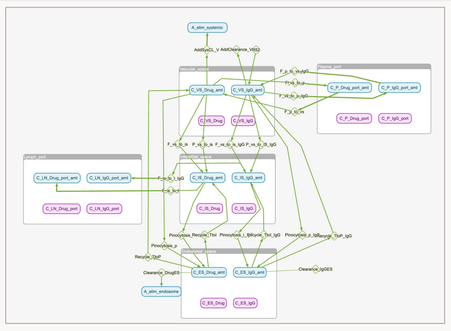
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One platform, one record. Build, run and report QSP models in one place, with the audit trail reviewers expect, backed by Certara's QSP team.

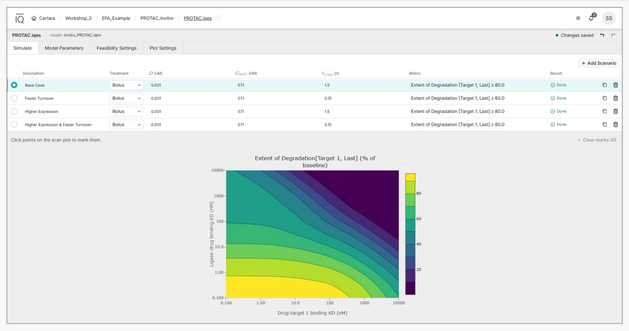
1 Certara IQ at a glance

IQ Design



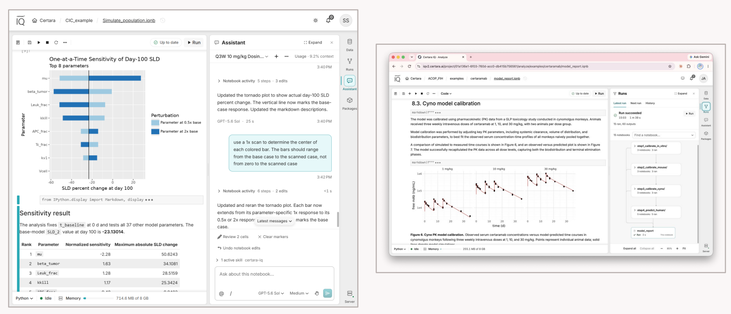
Build large models from reusable modules
Join sub-models into one platform model; IQ generates the equations

IQ Explore



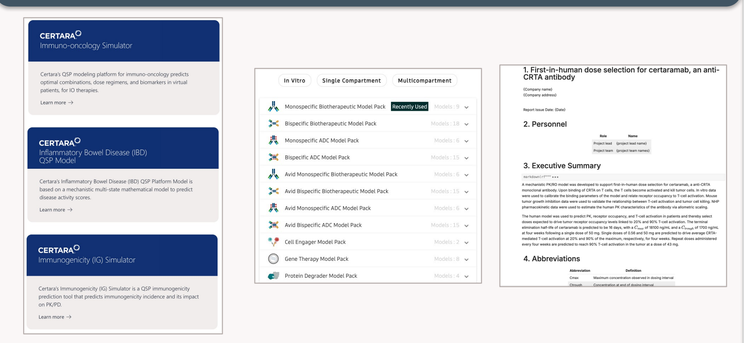
What-if scenarios with no code
Each row is a scenario; the heat map shows how drug properties change the response

IQ Analyze with Certara AI



R and Python notebooks with an AI agent
The agent writes and fixes code; workflows update the model report

IQ Library



Platform disease models and model packs
With workflow and report templates, such as a first-in-human (FIH) report

Connects to your tools

- **Simcyp · PBPK**
- **Phoenix NLME · population PK/PD**
- **CODEX · clinical outcomes**
- **Import and export · SBML · MATLAB · SimBiology**

Your team, supported by Certara

Your modelers, biologists and project teams work in one shared project, with Certara's QSP consultants alongside when you need them.

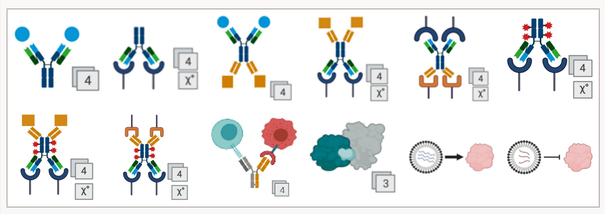
75+ QSP scientists	**700+** projects
275+ clients	**350+** years of combined experience

2 What regulators ask at each step, and where IQ helps

	Plan	Build	Evaluate	Report	Update
ICH M15 [1]	Question of interest, context of use, model risk	Documented model and assumptions	Verification, validation, applicability	Analysis plan and report	Refine as evidence accrues
FDA QSP MABEL draft [2]	State question, context of use and risk	Sourced parameters; documented code	Same-mechanism validation; sensitivity, uncertainty	QSP study report with assumptions	Early monitoring; refine before escalating
FDA Fit-for-Purpose [3]	Context of use that spans programs	Reusable platform model, fully documented	Validation driven by context of use	Public determination	Update plan and support
Certara IQ	**FIH and RP2D workflow templates**	**Library models; unit checks on every edit**	**Fits, sensitivity, virtual populations on HPC**	**Report templates; audit trail**	**Versioned projects; pinned environments**

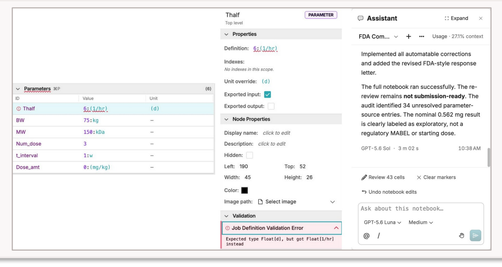
3 Start from a validated model, not a blank page

- Disease and pharmacology model libraries
- Antibodies, ADCs, TCEs, degraders, mRNA, siRNA
- FIH and RP2D workflow templates
- Validation code and documentation included



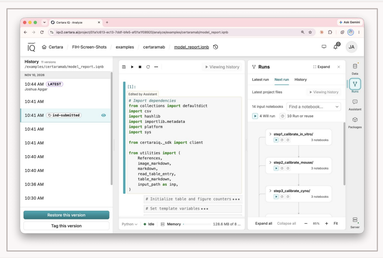
4 Errors caught as you build

- Units and stoichiometry checked on every edit
- Equations generated from the diagram or text
- Modules keep large models readable
- AI agent flags issues; you approve each change



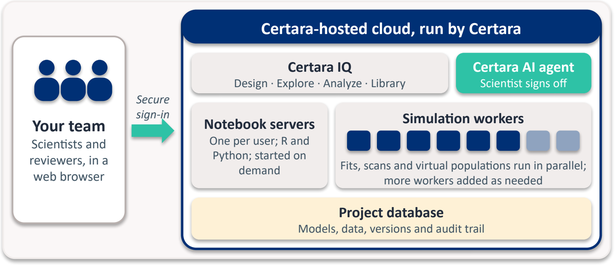
5 Every result fully traceable

- Tag, restore or clone any version
- Pinned software environments
- Data and model provenance
- Audit trail, roles and permissions



6 Scale without servers

- Compiled models run in parallel in the cloud
- Fits, sensitivity analysis and virtual populations
- No servers to install or manage



- One platform for the QSP life cycle: plan, build, evaluate, report, update
- AI-assisted, with a scientist approving every change
- Hosted and run by Certara; ISO/IEC 27001 and SOC 2 compliant

Ask for a demo or a trial license

See IQ live at this poster, or email joshua.apgar@certara.com.
Talk: "Model Credibility Is a Patient Safety Issue", Day 1, 12:30 pm.

Contact: joshua.apgar@certara.com

Some features shown are in development and will be available in future releases.

1 ICH M15: General principles for model-informed drug development. ICH Step 4, January 2026; FDA final guidance, June 2026. 2 US FDA. QSP-based dose selection for MABEL in FIH trials. Draft guidance, June 2026. 3 US FDA. Fit-for-Purpose initiative.

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