

IQANOVA MIDD FOUNDATION PACKAGE

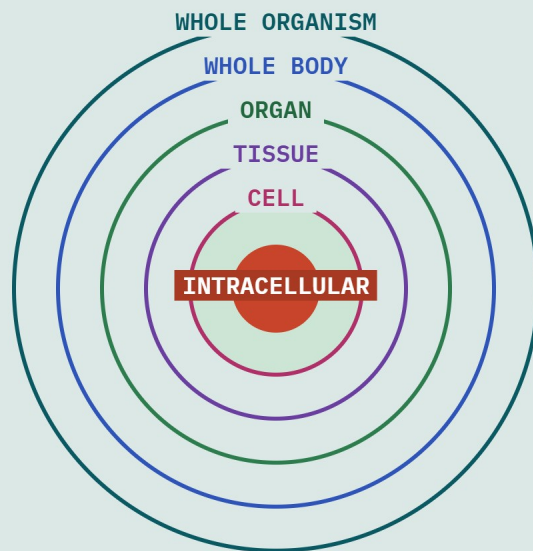
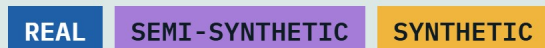
Models you can audit and trust.

One versioned ZIP: executable model, data, reports, manuscripts, patent screens, due diligence and regulatory drafts, each file labelled by evidence status.

Any scale. Any MIDD model family.



DATA, GRADED BY ORIGIN



SCAFFOLD · SUPPLIED
SEPARATELY

EHMN2027

Intracellular and cellular model family

- Thermodynamic metabolic core
- Cytokine networks
- 1,000 microbiome models integrated into the scaffold
- Transcription networks
- Kinetic models

22

Critic checks before any claim

4

Status axes on every file

D0-D10

Diligence at every stage

1 month

Standard delivery from the agreed brief

1 week

Accelerated, for eligible requests

Pricing

To be discussed; depends on stage and scope

REQUEST A MODEL

iqanova.org/ai-midd
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Inside the ZIP

Nineteen folders, organised so a reviewer can find, rerun and check every result.

FOLDER	WHAT IT HOLDS
00_START_HERE	README, model card, release status, licences, checksums
01_SCOPE_AND_LINEAGE	Intent contracts, backbone fingerprint, lineage, caveats
02_EVIDENCE	Literature report, ledgers, real-data extracts, rights
03_MODELS	Native model, SBML branches, equations, model tables
04_SIMULATION	Code, pinned environment, SED-ML, OMEX, replay logs
05_SYNTHETIC_DATA	Semi-synthetic and synthetic datasets, seeds, splits, QC
06_CALIBRATION	Parameters, fit configuration, calibration report
07_VERIFICATION_AND_VALIDATION	Rate-law, unit and Critic audits; V&V; claim warnings
08_ANALYSES	Sensitivity, identifiability, uncertainty, virtual patients
09_DIAGRAMS_AND_FIGURES	Architecture, pathway, PK/PD diagrams; editable sources
10_REPORTS	Model and regulatory reports; manuscripts on request
11_PROMPTS_AND_RUN_HISTORY	Exact prompts, checksums, run settings, update log
12_HTML_OVERVIEW	Offline ATLAS model page with working relative links
13_LIFECYCLE	D0–D10 memos, risk registers, gap matrices, gates
14_REGULATORY_CROSS_REFERENCES	Guidance register, CTD module maps, MIDD documents
15_RISK_AND_GOVERNANCE	Overall risk register, risk history, remediation plan
16_LIFECYCLE_PROMPTS	Lifecycle subprompt, document catalogue, settings
17_AI_SURROGATES	Surrogate assets and benchmarks · when scoped
18_DIGITAL_INTERFACES	Dashboard exports and API-ready schemas · when scoped

DATA IN THREE GRADES · EVERY DATASET IS LABELLED

REAL

Trial arms, literature values, digitised figures and your supplied data, with provenance. Shipped where rights permit.

SEMI-SYNTHETIC

Observed inputs plus model-generated components; the origin of every variable is identified.

SYNTHETIC

Virtual patients or systems, latent truth and noisy observations, with seeds and QC. Generator code not supplied.

ILLUSTRATIVE ZIP SIZES

Edition	Compressed	Extracted	Assumed data volume
Compact	20–75 MB	60–250 MB	Small demonstration datasets
Standard	75–400 MB	0.25–1.5 GB	About 1–15 million long-format rows
Lifecycle	100–750 MB	0.3–3 GB	Draft dossiers plus model and data
Expanded	0.4–2+ GB	1.5–10+ GB	Larger populations and repeated runs

Planning estimates in decimal units, not measured releases. Large spatial or population datasets can add many GB.

OUTPUT LIBRARY

358 outputs in nine families

Everything the IQANOVA prompt set can generate, from executable model to manuscript, patent screen and regulatory dossier. 347 come from the current prompts; 11 are extension modules. Your order selects what applies.



Outputs per family. In 08, the four records repeated at each stage are counted once per stage.

01 35 Model & release model_card.md {MODEL}___{STATE}.xml COMBINE.omex run_config.yaml manifest.json MP 0K-0L · MX · 001-007	02 43 Fidelity & QC audit intent_contract.md rate_law_comparison.xlsx critic_matrix.xlsx replay_audit.xlsx prompt_update_log.md MP 0X-0J · 5A · 15	03 17 Evidence & literature literature_search_log.csv evidence_delta.csv source_ledger.csv claim_registry.json biomarker_observability.csv MP 0.0 · DD §3-7 · 004
04 57 Analyses & data gsa_results.json vp_therapy_results.csv REAL observed_data_extracts SEMI semi_synthetic_*.csv SYN all_synthetic_data.csv MP 2A-10 · 005-014 · PKG 02, 05	05 25 Reports & manuscripts manuscript_final.docx preprint.docx response_letter.docx atlas_model_full.html ◆ graphical_abstract.svg MP 11-14A · 017-018 · EXT	06 15 IP, patents & rights novelty_ip_screening.docx source_rights_register.xlsx ◆ patent_landscape_report ◆ competitor_patent_map.xlsx ◆ invention_disclosure_draft LC D0-D1 · 026 · EXT
07 23 Due diligence due_diligence_report.docx four_lane_scorecard metric_table.csv frozen_prediction.json value_of_information_plan DD v5.1 / v6.0 · LC D0	08 120 Regulatory lifecycle investigator_brochure.docx clinical_protocol.docx ctd_module2_summaries midd_evidence_assessment psur_pbrrer.docx LC D0-D10 · MX · MP 1, 12	09 23 Digital & updates surrogate_model_card.md applicability_envelope.json dashboard.html io_schema.json validation_dossier_delta.md 019-025 · subscription

Source key. MP Master Prompt v2.21 · DD Due-Diligence Prompts v5.1 and v6.0 · LC Lifecycle Subprompt v5.0 · MX MIDD Addendum v5.0 · 001-026 website output groups · PKG release-guide folder.

◆ **Extension module**, quoted on request. Every other file is core or scoped to the order. Names, descriptions and sources for all 358 are in the Complete output catalogue.

Manuscripts and patents

The same audited record that builds the model drafts the paper and briefs your patent counsel, so claims never run ahead of the evidence.

05 From model to manuscript

1 • FIGURES AND CLAIM CHECK

Figure1-N.png
claim_warning_table.xlsx

2 • MANUSCRIPT

manuscript_final.docx
manuscript_final.pdf

3 • JOURNAL PACKAGE

cover_letter.docx
supp_index.docx

4 • MEDRXIV PREPRINT

preprint.docx
metadata.json

5 • REVIEWER RESPONSE

reviewer_comment_matrix.xlsx
manuscript_tracked.docx
response_letter.docx

6 • ATLAS AND TALKS

atlas_model_full.html
poster_draft.pdf
presentation_draft.pptx

WORDING RULES APPLIED TO EVERY CLAIM

No executable source retrieved: **paper-faithful reconstruction**, never exact reproduction.

No external validation: **hypothesis-generating**.

Synthetic or surrogate data: **surrogate-calibrated**, never clinically validated.

Expert-found errors are stated in the Discussion, with the fix.

◆ Extensions: conference abstract, plain-language summary, graphical abstract. Submission and publication remain the authors' decision.

06 IP and patent intelligence

IN EVERY RUN

Novelty and patent screen for AI-designed candidates
Patents searched with literature, trials and regulation
IP assumptions in every stage diligence memo
IP and data-rights risks in every risk register
Source-rights and redistribution registers
Newly published patents as subscription triggers

◆ EXTENSION MODULES

Patent landscape and white-space report
Competitor patent map and prior-art search log
Claim chart against key claims, for counsel
Patent term, SPC and exclusivity timeline
Invention disclosure draft from the run
Provisional specification drafting support

Screens and drafts support a registered patent attorney. They are not freedom-to-operate or patentability opinions, and nothing is filed on your behalf. Extension modules are quoted on request.

07 • DECISION-GRADE DUE DILIGENCE

Decisions, not just models

A target, asset and model diligence report for licensing, investment and portfolio committees. The model is an audited input, never the source of truth.

Every report ends in one call:

GO

CONDITIONAL GO

HOLD

NO-GO

Target-indication

Human causal evidence, clinical validation, pathway redundancy, biomarker linkage, modality fit.

CAP ≤69 without human target evidence

Asset execution and safety

PK/PD coverage, efficacy, safety window, CMC and developability, regimen and adherence.

CAP ≤49 with a serious unmitigated safety signal

Competitive, regulatory, corporate

TPP advantage, precedent, preference, access, pipeline durability and sponsor execution.

Cross-trial comparisons flagged indirect

Model credibility

Verification, biology, parameter provenance, validation independence, uncertainty, reproducibility.

CAP ≤59 with no frozen prospective test

THE REPORT, SECTION BY SECTION

01 One-page decision brief

02 Decision contract

03 Source ledger, timelines

04 Target-indication

05 Asset pharmacology

06 Safety risk register

07 Competition and failures

08 Model cross-examination

09 Estimand and event audit

10 Metrics and uncertainty

11 Four-lane scorecard

12 PoS scenarios

13 Value of information

14 Frozen prediction, kill criteria

15 Provenance and run log

LIVING LITERATURE • EVERY SOURCE GRADED AND DATED

A1

A2

B

C

D

E

regulator-confirmed down to in-vitro or assumption

Each update classifies evidence as new, updated, contradictory, withdrawn or unchanged, and states its effect on the decision, the model and the score.

MACHINE-READABLE FILES

literature_search_log.csv • source_ledger.csv • evidence_delta.csv • claim_registry.json • biomarker_observability.csv • metric_table.csv • frozen_prediction.json

Stage diligence memos come with every package. The full report is commissioned separately; price depends on stage and scope.

To be discussed

Scores and probabilities of success are structured judgements unless empirically calibrated. Not investment advice.

08 • REGULATORY LIFECYCLE DOSSIER

Risk assessed at every stage

From target to post-market, each stage receives four records and its own documents, mapped to UK, EU and US routes through an applicability matrix.

Diligence memo .docx	Risk register .xlsx	Regulatory gap matrix .xlsx	Gate decision .json
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STAGE		KEY DOCUMENTS	PRINCIPAL RISKS
D0	Target and intent	TPP, target-indication diligence, MIDD analysis plan	Biological relevance, unmet need
D1	AI candidate design	Candidate registry, AI model card, novelty and patent screen	Leakage, bias, IP and data rights
D2	Hit and lead	Assay evidence review, selectivity, early ADME and safety	Assay artefacts, off-target effects
D3	Lead optimisation	Candidate selection, MIDD translation, combination hypotheses	Translation, safety margins
D4	IND-enabling, CMC	Nonclinical plan, toxicology summaries, CMC quality package	Species relevance, impurities
D5	Trial authorisation	IND or CTA index, investigator brochure, IMPD, protocol	Human dose, participant safety
D6	Phase I	Protocol and SAP, PK/PD and tolerability, DSUR inputs	Exposure, emerging signals
D7	Phase II	Proof-of-concept design, dose selection and benefit-risk	Dose choice, endpoint validity
D8	Phase III	Pivotal protocol, integrated summaries, gap review	Estimands, multiplicity, rare harms
D9	Submission	CTD Modules 1–5, label, RMP or REMS, MIDD report	Evidence sufficiency, consistency
D10	Post-market	PV and signal plan, PSUR/PBRER, variations	New signals, control effectiveness

Content

TEMPLATE • DRAFT_FROM_EVIDENCE • REVIEWED

Evidence

MISSING • PARTIAL • AVAILABLE

Applicability

TO_ASSESS • APPLICABLE • NOT_APPLICABLE

Decision

PASS • HOLD • BLOCKED

Templates and drafts never stand in for studies, GxP records, signatures or regulator decisions. A ZIP is not a validated eCTD. REVIEWED requires a recorded reviewer, date and scope.

Order a model

1 • BRIEF

Area, targets, drugs, scale, model family, question, endpoints, stage, markets

2 • SCOPE AND QUOTE

Outputs, data grades, licence and delivery option agreed in writing

3 • BUILD THROUGH GATES

Fidelity, Critic and claim checks; HOLDS stay visible

4 • RELEASE

Versioned ZIP, handover and one technical revision

Delivery	Target	Price
Standard	1 calendar month	To be discussed
Accelerated	1 week, if eligible	To be discussed

Price depends on the development stage, model family and scale, number of targets, drugs and combinations, data and licence. Accelerated delivery needs a reusable backbone and adequate evidence.

Keep it current: two ways to subscribe

A • MONTHLY

steady cadence

Evidence Watch

One model; weekly source checks, monthly impact brief

Model Maintenance

One model; up to one minor checked release per quarter

Portfolio

Up to three models; one shared minor release per month

Monthly fee

To be discussed

B • EVENT-TRIGGERED

new evidence, new model

A qualifying event starts an impact review. If the evidence justifies it, you receive a new model version or a new model.

Clinical results

Experimental data

New drug

Target association

Published patent

Safety finding

Impact review and new model

To be discussed

Prior version frozen; change log, repeat checks and new manifest with every release.

All prices are to be discussed and depend on the development stage, scope, model complexity, data and licence.

REQUEST A MODEL

Send your brief. We return a scoped quote.

iqanova.org/ai-midd sales@iqanova.org



The written quote defines price, scope and licence. Monitoring starts only under an activated service agreement. Research use only.