THERASIK · PRODUCT WHITEPAPER

TheraMab: AI-Driven Therapeutic Antibody Developability Platform

Developability assessment, optimization, and development for humanized and fully human antib

One platform takes an antibody from a non-human sequence to a developable candidate: humanization design, developability assessment, and CMC formulation optimization and advice.



TheraMab

Humanization · Developability · CMC formulation

November 2026 · TheraSik

This whitepaper describes the product as it is designed today and the capabilities already validated. The content is for scientific research and early R&D reference only; it does not constitute a basis for clinical decisions, diagnosis, treatment, or regulatory submission.

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The product demo video (about 4 min 41 s) is referenced in Section 2. Because of the file format, this PDF includes only the cover frame; the full video is available at https://insynbio.com/theramab/. To request a trial, email jhuang@insynbio.com.

01 Overview

TheraMab brings together, on one platform, the three things needed to take an antibody from a non-human sequence to a developable candidate: humanization design, developability assessment, and CMC formulation optimization and advice. From one pair of heavy and light chains, a client obtains several humanization options, the risk positions of each option, actionable optimized sequences, and formulation advice for both subcutaneous and intravenous administration.

Highlights

- **One continuous workflow, no tool-switching**: humanization, assessment, optimization, and formulation advice are done in one place, and optimized sequences can go straight back into the assessment table to be re-evaluated.
- **Privacy and information security as a premise**: each client's sequences and results belong only to their own account, and neither pages nor interfaces expose internal details of the algorithms or databases.

- **Results with a sense of position**: each parameter is placed within a reference range derived from our clinical observations and estimates, shown with a clear position label rather than as an isolated number.

Antibodies that are already fully human or humanized (including sequences designed by other software) can also go directly into developability assessment. This product is for scientific research and early R&D reference only; it does not constitute a basis for clinical decisions, diagnosis, treatment, or regulatory submission.

02 Product demo video

A walkthrough of the TheraMab web edition (about 4 min 41 s). The demo uses public example antibodies and was recorded in a separate test environment; it contains no client data. The full video can be viewed on the web page: https://insynbio.com/theramab/



▲ Product demo video (web-edition walkthrough, about 4 min 41 s). Full video at https://insynbio.com/theramab/

03 Background and challenges

In early antibody R&D, sequence design and developability judgement are usually split across several tools and several people. It is hard to connect the information, and three problems recur.

1. **Humanization and developability are disconnected**: humanization options are made in one tool and developability is assessed in another; changing a sequence means exporting and importing again, and the trade-offs of back-mutations and their effect on developability are not visible on the same chart.
2. **Risk is only numbers, with no sense of position**: a single physicochemical parameter lacks a reference, so the team cannot tell whether a value is high or low, or in which direction to optimize.
3. **Formulation and sequence are considered separately**: formulation is only thought about after the sequence is fixed, by which point viscosity or aggregation problems are already late; there is no direct link between risk sites and the corresponding formulation levers.

There is a further concern for external use: sequences are a client's most core asset, and a tool is hard to accept if it lets multiple users' data mix together, or if it exposes internal algorithm and database details on its pages. TheraMab is designed to make the three tasks above into one continuous workflow, while treating privacy and information security as a premise of the product rather than an add-on.

04 Product overview

TheraMab is offered as a web edition and a desktop edition, serving two kinds of use and sharing the same assessment logic and result interpretation.

Edition	Suited to	Data form	Status
Web edition	Team collaboration, multi-user trials, ready to use with no install	Sequences and results are kept under the account and isolated between accounts; trial example sequences are shared read-only	Live, opened by account invitation
Desktop edition	Settings more sensitive about data leaving the premises; runs on the local machine	Data processed locally	Available on request; let's talk

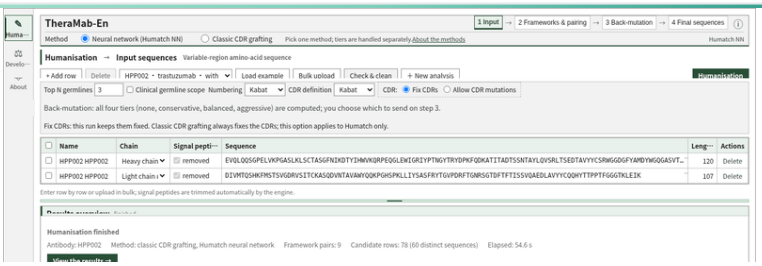
What a client receives: several humanization options; a humanness and developability assessment of each option; risk sites and substitution suggestions; optimized sequences and their re-assessment; subcutaneous and intravenous formulation advice; and exportable reports, score tables, and sequence files.

Two kinds of input: one is a non-human antibody (humanize first, then assess); the other is a sequence that is already fully human or humanized by other software (go directly to developability assessment).

05 Workflow

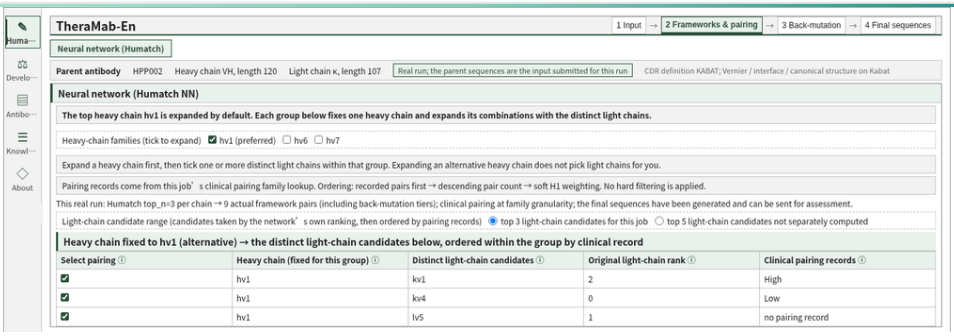
From input sequence to formulation advice, the client works through one connected flow, and the result of each step carries into the next.

1. **Input**: paste or upload heavy and light chains (CSV, FASTA, Excel; templates and format notes are provided). Non-human antibodies go through humanization; sequences that are already fully human or humanized can go directly to developability assessment.



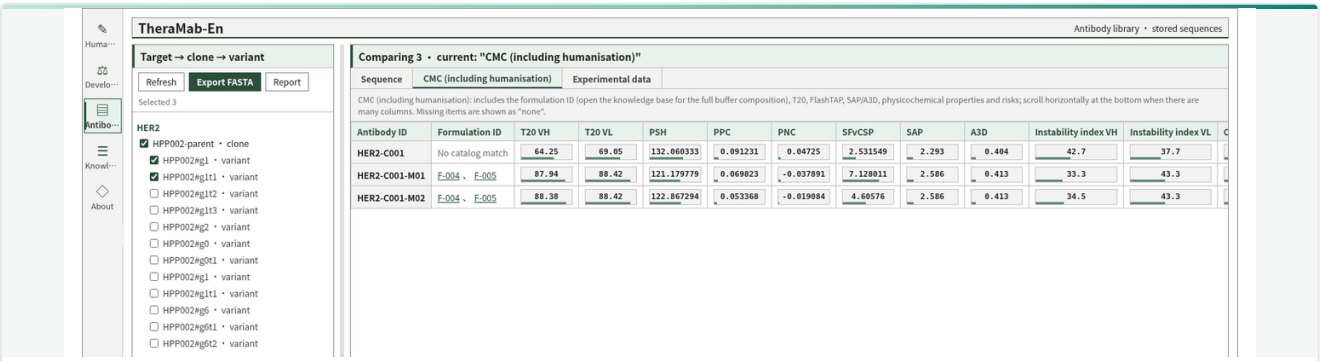
▲ Fig. 1: Sequence input page (the demo has loaded the heavy and light chains of the public example antibody).

2. **Humanization**: the system offers several framework pairings, each with different back-mutation levels (none, conservative, balanced, aggressive). The client selects the pairings of interest, and later assessment is shown only for the selected pairings.



▲ Fig. 2: Framework and pairing — candidate light chains and the number of pairing records.

3. **Assessment**: humanness, physicochemical developability, FlashTAP, and a CMC summary. Each parameter is shown within a reference range on a position map and radar chart, with axis notes and result analysis.
4. **Optimization**: risk sites are split into CDR and FR tables. FR sites carry substitution suggestions; once ticked, an optimized sequence is generated in one click, can be exported, and can be added back into the assessment table.
5. **Re-assessment**: an optimized sequence added back to the assessment table is re-evaluated automatically, with results for whole-antibody, CDR-only, and FR-only views, so the client can see directly whether the optimization improved key parameters (steps 4 to 5 can be repeated).
6. **Formulation advice**: tiered subcutaneous and intravenous formulation advice, formulation numbers, and marketed molecules physicochemically similar to the client's sequence; the formulation lever for each risk site links to a specific formulation entry in the knowledge base.
7. **Library and report**: candidate sequences can enter the client's own account library, and a comprehensive report including the formulation advice and its rationale is generated.



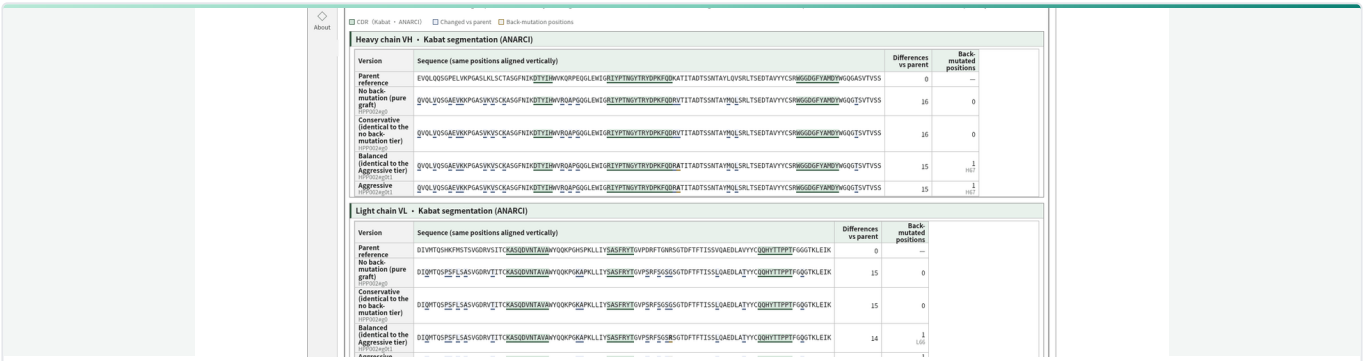
▲ Fig. 3: The antibody library is organized by target, clone, and variant, and CMC parameters can be compared side by side.

Analysis state is saved per job in the client's own browser, so after viewing the knowledge base or switching pages the client can return to the previous results; "New analysis" clears everything in one click to start over, without affecting sequences already in the library.

06 Core capabilities

Humanization

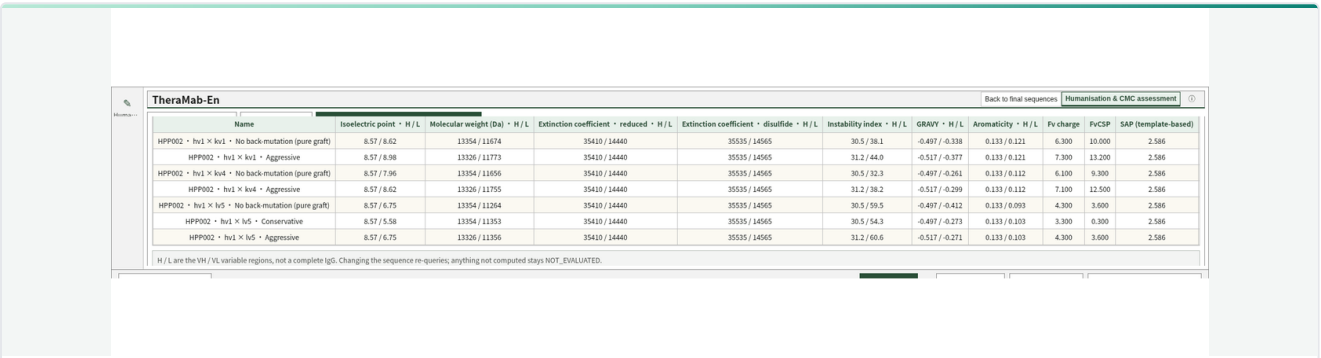
For a non-human antibody, two routes are offered at once: classic CDR grafting, and a neural-network (NN) design that keeps more of the parental framework. Both routes have four back-mutation levels (none, conservative, balanced, aggressive) under the same back-mutation rules. The difference is the starting point: CDR grafting transplants the whole germline framework and so has more back-mutation positions to consider, while NN keeps most of the parental framework and has fewer. The client selects the framework pairings of interest at step 3, and later assessment is shown only for the selected pairings.



▲ Fig. 4: The final sequence aligned to the parent (blue marks changes, yellow marks back-mutation positions).

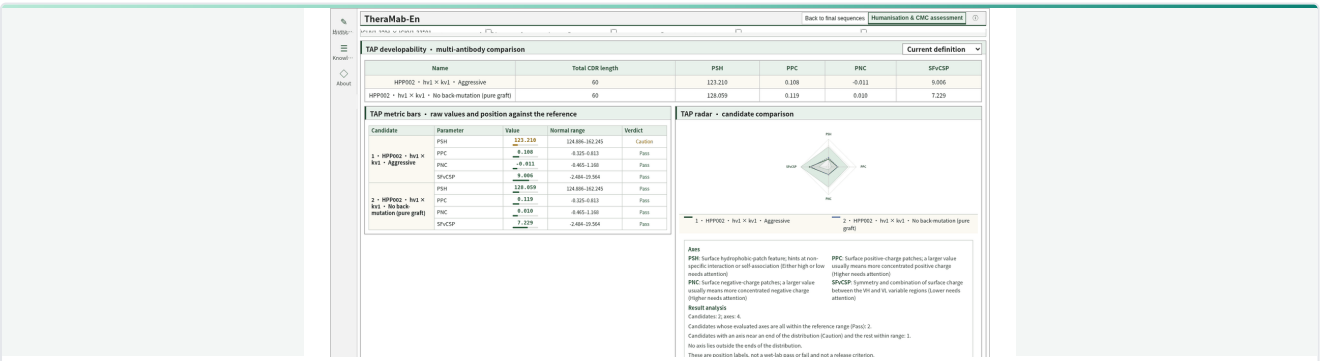
Developability assessment

- **Physicochemical and structural parameters**: instability index, hydrophobicity (GRAVY), chemical risk sites, pI, Fv net charge, the viscosity indicator FvCSP, spatial aggregation propensity (SAP), and aggregation propensity (A3D).



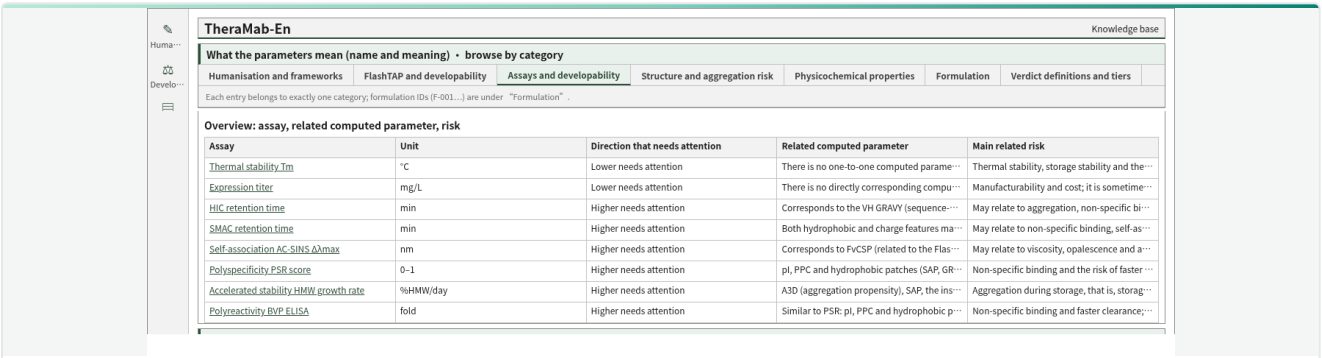
▲ Fig. 5: Physicochemical and structural parameter table, one row per candidate.

- **FlashTAP**: a fast, TAP-like risk indicator.
- **Position map and radar chart**: each parameter is placed within a reference range derived from our clinical observations and estimates, shown with "pass, caution, exceeds, falls short" position labels, with axis notes and result analysis. These are position labels, not a pass/fail judgement from wet-lab work, and not a release criterion.



▲ Fig. 6: Position map and radar chart (the light-green band is the common range).

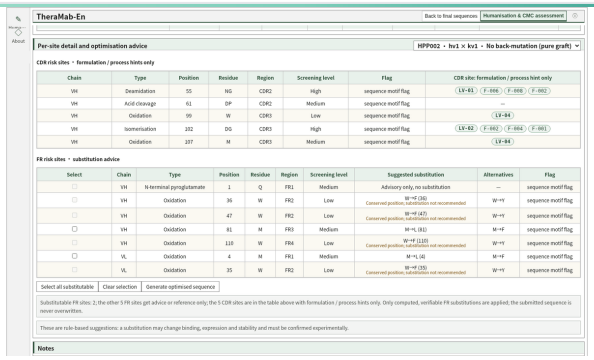
- **Experimental-value entry table**: clients enter their own measured values (Tm, expression, HIC, SMAC, AC-SINS, PSR, accelerated-stability slope, BVP, etc.); the system marks the position against thresholds and reminds the user to run a same-condition head-to-head comparison with a clinical antibody.
- **Knowledge base**: an "Assays and developability" page explains the meaning, risk direction, relationship to developability, and limitations of each experimental and computed parameter.



▲ Fig. 7: Knowledge base, "Assays and developability" page.

Risk-site optimization

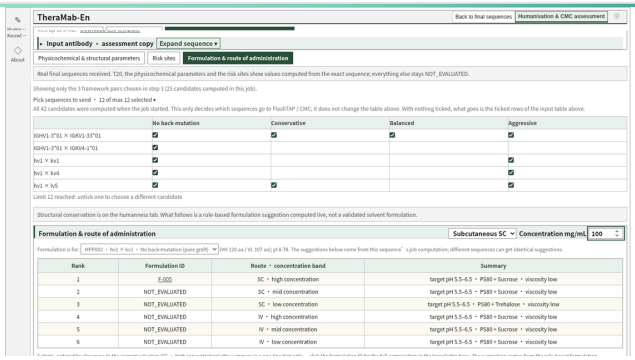
CDR and FR risk sites are presented separately. CDR sites involve binding, so only formulation and process hints are given; FR sites carry specific substitution suggestions and alternatives, staying conservative at positions such as conserved tryptophans. Once the client ticks a selection, an optimized sequence is generated in one click, can be exported as FASTA, and can be added back into the assessment table to be re-evaluated, using the whole-antibody, CDR-only, and FR-only views to see whether it improved.



▲ Fig. 8: Risk sites and optimization suggestions (CDR / FR split tables; an optimized sequence can be generated).

CMC formulation optimization and advice

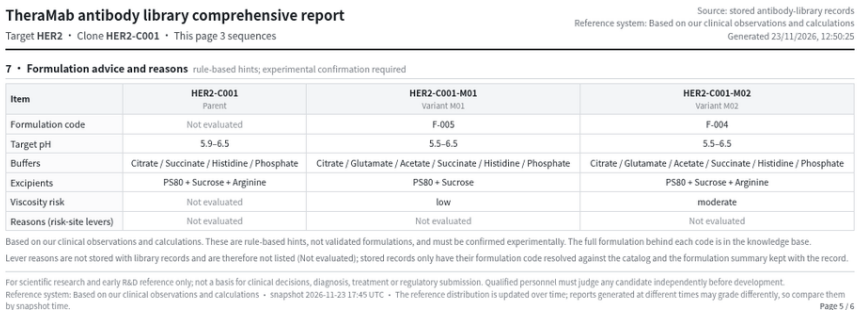
- **Tiered advice**: for the subcutaneous and intravenous administration routes, each with high, medium, and low concentration tiers, giving pH, buffer system, excipients, and viscosity risk.



▲ Fig. 9: Submission choices and formulation advice (subcutaneous and intravenous; high, medium, and low concentration tiers).

- **Formulation numbers and comparison**: a formulation number is given, along with marketed molecules physicochemically similar to the client's sequence as references.
- **Levers linked to formulations**: each risk site corresponds to a formulation lever (for example, an oxidation site corresponds to practices that suppress oxidation), linked to specific formulation entries in the knowledge base (a few references at most).

- **Report**: a "Formulation advice and rationale" page lists composition, pH, excipients, viscosity notes, and lever rationale, marked as rule-based hints that need experimental validation.



TheraMab antibody library comprehensive report

Target HER2 · Clone HER2-C001 · This page 3 sequences

Source: stored antibody-library records
Reference system: Based on our clinical observations and calculations
Generated 23/11/2026, 12:50:25

7 · Formulation advice and reasons rule-based hints; experimental confirmation required

Item	HER2-C001 Parent	HER2-C001-M01 Variant M01	HER2-C001-M02 Variant M02
Formulation code	Not evaluated	F-005	F-004
Target pH	5.9–6.5	5.5–6.5	5.5–6.5
Buffers	Citrate / Succinate / Histidine / Phosphate	Citrate / Glutamate / Acetate / Succinate / Histidine / Phosphate	Citrate / Glutamate / Acetate / Succinate / Histidine / Phosphate
Excipients	PS80 + Sucrose + Arginine	PS80 + Sucrose	PS80 + Sucrose + Arginine
Viscosity risk	Not evaluated	low	moderate
Reasons (risk-site levers)	Not evaluated	Not evaluated	Not evaluated

Based on our clinical observations and calculations. These are rule-based hints, not validated formulations, and must be confirmed experimentally. The full formulation behind each code is in the knowledge base.
Lever reasons are not stored with library records and are therefore not listed (Not evaluated); stored records only have their formulation code resolved against the catalog and the formulation summary kept with the record.

For scientific research and early R&D reference only; not a basis for clinical decisions, diagnosis, treatment or regulatory submission. Qualified personnel must judge any candidate independently before development.
Reference system: Based on our clinical observations and calculations · snapshot 2026-11-23 17:45 UTC · The reference distribution is updated over time; reports generated at different times may grade differently, so compare them by snapshot time.
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▲ Fig. 10: Comprehensive report, "Formulation advice and rationale" (rule-based hints; require experimental validation).

Formulation-related output is advice based on rules and surrogate indicators; it is not a viscosity-prediction model and not an experimentally validated conclusion.

07 Privacy and information security

Privacy and information security are a premise of the product. The table below lists the measures already implemented in the web edition; each has been independently reviewed and validated.

Aspect	Measure
Data isolation	Each client's sequence library and jobs are kept under their own account and invisible to other accounts; accessing another account's job and accessing a non-existent job return exactly the same result; trial example sequences are shared read-only.
Access control	Login authentication, with accounts opened by our invitation; account identity is passed in and verified by the access layer, and identity headers forged by the client are discarded; without a valid identity, write operations are refused outright.
Algorithm and database confidentiality	Pages and interfaces do not show source names, database names, sample sizes, or literature citations; external output drops internal fields and uses neutral codes for internal references; page scripts are minified and stripped of comments; public interfaces are rate-limited.
Network security	HTTPS site-wide, with HSTS, security headers, hidden server version, rate limiting, and request-body size limits; the old direct-connect ports are closed to the outside.
Client-side state	Analysis state and drafts are stored only in the client's own browser and not uploaded to the server; "New analysis" clears them in one click.
Backup and recovery	Daily consistent backups of the sequence library and account information, weekly recovery tests, health checks, and alerting.
Audit and change	Every release is first independently reviewed, then accepted in an isolated environment, independently verified by another person, with a rollback option kept ready at all times.

Data statement: the platform stores the sequences, computed results, and library entries a client submits. Only the client's own account can see them; operations staff access them only for operations and for deletion at the client's request. They are kept until the client asks for deletion, after which they remain in backups for at most about two more months. For deletion requests, contact the TheraMab team member who opened your account.

Boundaries, stated plainly: at present we use account-level data isolation and access control, without third-party security certification or an independent penetration test; backups are currently on the same host, with an off-site copy not yet in place; operations staff can read private data files at the server level. For highly sensitive sequences, we recommend the locally run desktop edition.

08 Inputs, outputs, and how to use

Stage	What is supported
Input	Paste the variable region or full sequence of the heavy and light chains into the text box (signal peptide and constant region are trimmed automatically); batch-upload CSV, FASTA, or Excel, with templates and format notes; up to 12 pairs assessed at a time.
Humanization result	Several framework pairings, with sequences for four back-mutation levels per pairing, plus a humanness and physicochemical assessment.
Assessment result	Position map, radar chart, parameter table, risk-site table, FlashTAP, and CMC summary.
Optimization result	Substitution suggestions and optimized sequences (exportable as FASTA, able to re-enter assessment).
Formulation result	Tiered subcutaneous and intravenous formulation advice, formulation numbers, and similar marketed molecules.
Export	Sequences (FASTA), score tables (CSV), and a comprehensive report (including a printable "Formulation advice and rationale" page).
Sequence library	Candidate sequences can enter the client's own account library, organized by target, clone, and variant; duplicate sequences are flagged as "already exists" and existing records are not overwritten.
Language	Chinese and English interfaces.

Sequences that are already fully human or humanized by other software go directly into assessment, with output of physicochemical parameters, FlashTAP, SAP and A3D, risk sites with regions, and formulation advice.

09 Scope and limitations

This is a reference tool for scientific research and early R&D. The following boundaries should be known to the client in advance.

- **Position labels are not experimental results**: "pass, caution, exceeds, falls short" indicate where a candidate sits within a reference range, not the success or failure of wet-lab work, and not a release condition. Thresholds change with experimental conditions, so a same-condition comparison with a clinical antibody is recommended.
- **Formulation is rule-based advice**: it is based on rules and surrogate indicators, not a viscosity-prediction model, and needs experimental validation.
- **Humanness comparison for external sequences has gaps**: for sequences that are already fully human or designed by other software, there is no OASis humanness score; when no parental sequence is provided, comparisons to the parent (loops, H3, Vernier, interface, back-mutations) are shown as not assessed.
- **Unsupported molecule formats**: single-chain antibodies (scFv) and nanobodies (VHH) are not supported at present.

- **Scale limits**: up to 12 pairs assessed at a time; the assessment interface allows at most 15 calls per 5 minutes.
- **Security boundary**: see "Boundaries, stated plainly" in the previous section.

This product is for scientific research and early R&D reference only; it does not constitute a basis for clinical decisions, diagnosis, treatment, or regulatory submission. Before any candidate enters development, it needs independent judgement by qualified personnel together with experiments and regulatory requirements.

10 Roadmap and statement

Coming soon (with the next version): on page 1, an "already fully human, go directly to developability analysis" option and a "New analysis" button; format notes and a CSV template for batch upload, with automatic assessment after import; formulation numbers, similar marketed molecules, and substitution suggestions for optimized sequences; restoring analysis state from any return path; and a data-and-privacy page.

Planned, scheduled as demand dictates:

- Connect OASis humanness scoring to the assessment of external sequences.
- Save formulation and lever rationale for newly added library sequences, so the comprehensive report is more complete for them.
- A feasibility study of high-concentration viscosity-prediction models (licensing, validation, compute).
- An off-site backup copy.

Statement: this whitepaper describes the product as it is designed today and the capabilities already validated. The content is for scientific research and early R&D reference only; it does not constitute a basis for clinical decisions, diagnosis, treatment, or regulatory submission, and does not guarantee a candidate's performance in experiments. Versions and features are as actually delivered.

11 Trial and contact

To trial TheraMab, or to request materials beyond this whitepaper, please email the TheraSik address. We open the web-edition trial by account invitation.

jhuang@insynbio.com