Makby

NEXT GENERATION NAMs PRECLINICAL DRUG TESTING

Oct 2026

Makby

Transform preclinical drug development by turning human biology into standardized, scalable, and testable tissue models

OUR APPROACH

Makby is an AI- and tissue-engineering-driven company developing standardized, human-relevant New Approach Methodologies (NAMs) for the next generation of preclinical drug testing.

By combining artificial intelligence, advanced tissue engineering, biomaterials, bioprinting, and multicellular human tissue models, Makby helps pharmaceutical, biotech, and medtech companies generate more predictive preclinical data while reducing reliance on conventional animal-based approaches.

From model design to validation, Makby supports the development of standardized and reproducible human tissue models tailored to specific biological questions, indications, and drug-development needs.

What Makby Offers

Preclinical Testing Services
Human-relevant platforms for ADME, toxicology, efficacy, and translational studies, supporting decision-making throughout preclinical development.

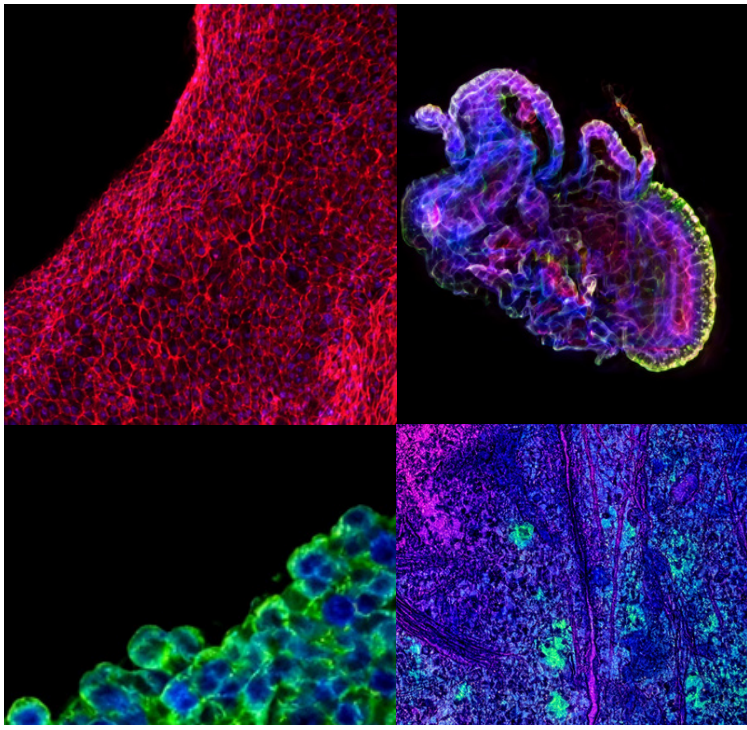
Ready-to-Use Human Tissue Models
Corneal, skin, intestinal, and other human-relevant tissue models designed for rapid integration into in-house preclinical testing workflows.

Custom NAMs Development as a Service
Indication-specific tissue models engineered around the biological mechanisms, endpoints, and testing requirements of each project.

AI-Driven Model Design & Tissue Engineering
Application of AI and advanced tissue-engineering approaches to support model optimization, characterization, and development of reproducible tissue platforms.

Bioprinting & Biomaterial/Scaffold Design
Design and fabrication of engineered biomaterials and scaffolds to recreate key structural and functional features of human tissues.

Partnerships & Co-Development
Collaborative development programs with pharmaceutical, biotechnology, and medical technology companies to create and validate next-generation NAMs.



Why Work with Makby?

- Human-relevant multicellular tissue models
- AI-enabled tissue engineering and model development
- Standardized and reproducible NAM platforms
- Advanced biomaterials and bioprinting capabilities
- Indication-specific model customization
- From concept and design to preclinical validation
- Built to improve translational relevance and reduce preclinical risk

From Human Biology to Predictive Preclinical Testing
Makby is helping transform preclinical drug development by turning human biology into standardized, scalable, and testable tissue models.

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SERIVCES & SOLUTIONS

	WHAT MAKBY CAN OFFER	WHAT PROBLEM CAN BE SOLVED
Testing services	ADME, toxicology, efficacy, translational studies	Generate decision-ready data without establishing capability internally
Standard tissue platforms	Skin, eye, respiratory, GI, oncology, BBB/neurovascular, oral, tendon	Obtain human-relevant experimental systems quickly
Custom NAM development	Indication-/mechanism-/endpoint-specific model engineering	Answer biological questions unsupported by standard models
Enabling technology & partnerships	AI model design, tissue engineering, bioprinting, biomaterials, co-development	Develop or improve next-generation models/platforms

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NAMs

Human Centric Models for Next-Generation Preclinical Drug Testing

Add the human dimension before entering the clinic

Ready-to-use and custom-engineered 3D tissue models designed to recapitulate human biology and complement conventional preclinical approaches with human-relevant evidence.

HUMAN-RELEVANT EVIDENCE	MECHANISTIC INSIGHT	BETTER-INFORMED DECISIONS
Across tissues & modalities	Efficacy • Safety • ADME	Candidate selection • Go / no-go

Select the model that fits your development question

A broad portfolio of human-relevant tissue systems, with custom engineering where needed.

Respiratory

- Nasal (HNEC) and tracheo-bronchial (HTEC) mucosa
- COPD disease models

Gastrointestinal

- Caco-2, primary organoid and Transwell®-like models
- Primary intestinal co-cultures incl. immune, endothelial and enteric neural cells

Skin & Eye

- Epidermal, full-thickness, synthetic-matrix and iPSC-derived skin organoids
- Corneal, retinal pigment epithelium, conjunctival and ex vivo cornea models

Immuno-Oncology

- Melanoma, lung adenocarcinoma, colon and breast cancer models

Neurovascular

- Patient-derived hiPSCs for neurovascular and blood–brain barrier modeling

Oral mucosa & Tendon

- Primary-cell or cell-line epidermal and co-culture oral models
- Perfused 3D fibrin hydrogel and 3D-bioprinted tendon models

From drug candidate to translational evidence

01 DRUG CANDIDATE
Biologics • RNA • LNP • Small molecules

02 SELECT MODEL
Skin • Eye • Lung • GI • TME and more

03 GENERATE HUMAN DATA
ADME • Efficacy • Safety

04 INFORM DECISIONS
Candidate selection • Go / no-go

Makby helps match your drug candidate to a human-relevant model and generate evidence across ADME, efficacy and safety.

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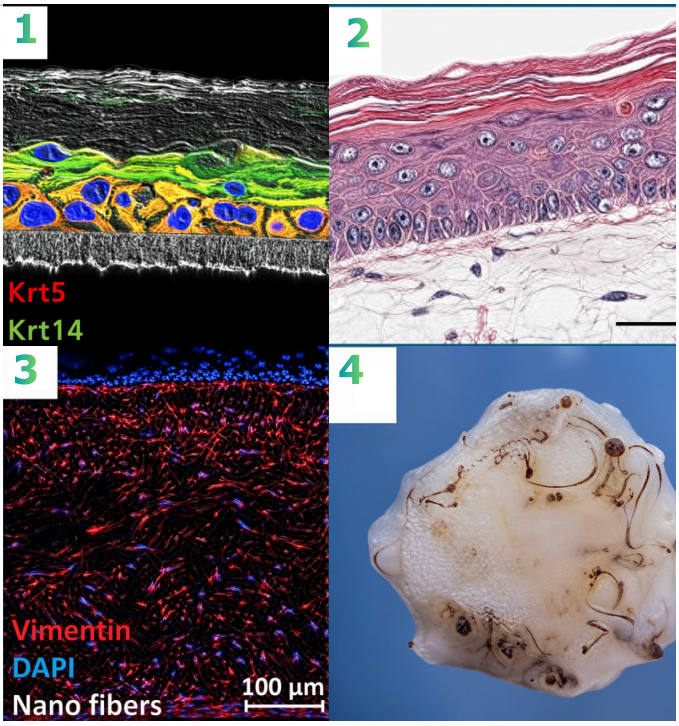
Skin

Accelerate Skin Drug Development with Human-Relevant NAMs

Gain early insight into formulation performance, drug distribution, efficacy and skin safety—supporting smarter candidate selection and optimized development.



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Understand Formulation & Barrier Interactions

See how your formulation interacts with human-relevant skin tissue and evaluate the impact of different concentrations and formulations on:

- Tissue viability
- Barrier integrity & TEER
- Histopathology
- Epidermal morphology
- Tight-junction & barrier proteins
- Inflammatory cytokines

Track Drug Disposition in Skin

Understand where your drug goes and how much gets there.
Characterize drug distribution across skin compartments:

- Stratum corneum deposition
- Epidermal concentration
- Dermal concentration
- Receptor-fluid concentration
- Penetration & flux
- Metabolite formation

Investigate Pharmacodynamics

Connect drug exposure with biological response.
When the relevant target is represented in the model, investigate:

- Target engagement
- Pathway modulation
- Pharmacodynamic biomarkers
- Dose–response relationships
- Exposure–response relationships

Evaluate Safety Earlier

Identify potential safety liabilities before they become costly development challenges.
Assess:

- Acute irritation
- Repeated-exposure effects
- Inflammatory responses
- Barrier disruption
- Cytotoxicity
- Phototoxicity

Available NAMs models

- Epidermal model [1]
- Full-thickness skin model [2]
- Fully synthetic matrix skin model [3]
- Human iPSC derived skin Organoids [4]
- Various diseased models

Available preclinical testing

- Skin irritation
- Skin corrosion
- Skin penetration
- Anti oxidative effects
- Anti-inflammatory effects
- Custom made test

Applications

- Wound healing
- Infection studies
- Compound testing

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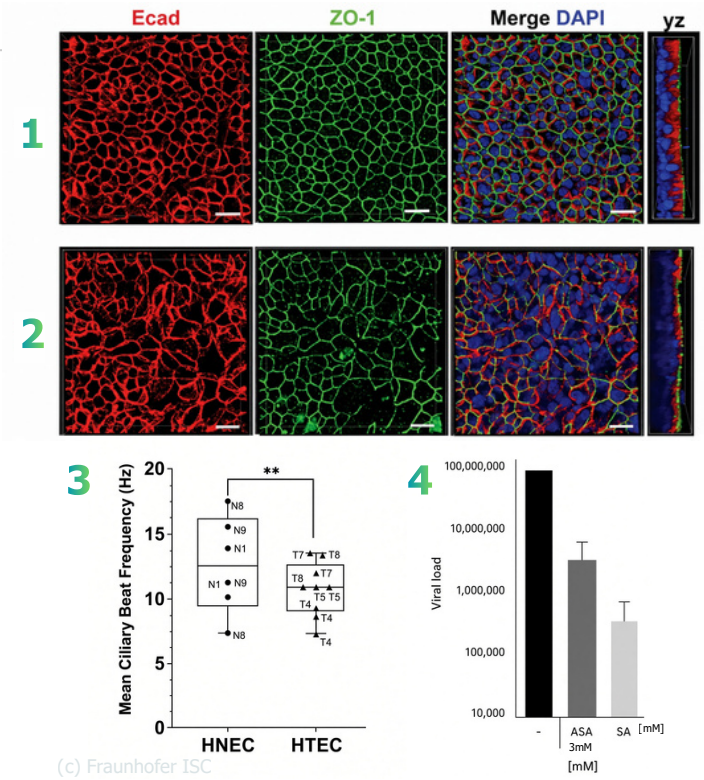
Human Respiratory

Translational models for smarter respiratory drug development

Evaluate respiratory drug candidates in physiologically relevant human airway models—before costly late-stage studies.
Go beyond "Does the compound affect a cell?" to "How does it affect human airway function?"



Primary Human Airway Models

Our primary human nasal and airway epithelial models reproduce key features of the respiratory epithelium, including:

- Differentiated epithelial cell types
- Ciliated and secretory cells
- Mucus production
- Barrier integrity
- Innate immune responses
- Mucociliary function
- Disease-relevant phenotypes

More Physiological Than Standard 2D Cultures

Our air–liquid interface (ALI) models recreate key features of the airway environment and enable measurement of:

- Ciliary beat and mucociliary transport
- Mucus production
- Barrier integrity and permeability
- Epithelial repair
- Cytokine and chemokine responses
- Cellular and molecular mechanisms

Patient-Derived COPD Models

Capture disease-relevant features of human COPD, including:

- Chronic inflammation
- Oxidative stress
- Barrier dysfunction
- Mucus hypersecretion
- Impaired mucociliary clearance
- Altered epithelial responses
- Exacerbation-associated responses

Test Multiple Therapeutic Modalities

Our human respiratory models support evaluation of:
Small molecules, Biologics, Peptides, Oligonucleotides, Antivirals & anti-infectives, Inhaled formulations, Nasal formulations, Combination therapies

Available NAMs models

- Nasal mucosa (HNEC) [1]
- Tracheo-bronchial mucosa (HTEC) [2]
- Chronic obstructive pulmonary disease (COPD)

Available preclinical testing

- Histology [1, 2]
- Ultrastructure
- Ciliary beating [3]
- Epithelial barrier integrity
- Mucin secretion
- Anti-inflammatory effects
- Antiviral effects [4]

Applications

- Mechanism of action
- Efficacy and dose–response
- Mucus & mucociliary function
- Epithelial barrier
- Inflammation
- Local tolerability
- Infection & host response

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NeuroVascular

Human CNS drug development platform integrating BBB penetration, neurovascular biology, neuronal pharmacology, and electrophysiology

Understanding whether a candidate can reach the brain—and what it does once it gets there—is one of the critical challenges in CNS drug development.

Our disease-specific NAM platform combines human induced pluripotent stem cell (hiPSC)-derived cells, BBB models and real-time neuronal activity measurements to generate functional data that can inform compound selection earlier in the discovery process.

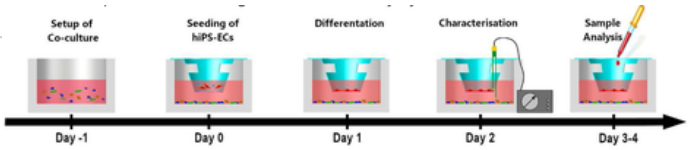
Human relevance by design
Patient-derived hiPSCs retain disease-associated genetics, enabling more human-relevant models of neurological disease.

Beyond BBB permeability
Assess BBB integrity, transporters, efflux, cellular exposure and neuronal responses—not just compound passage.

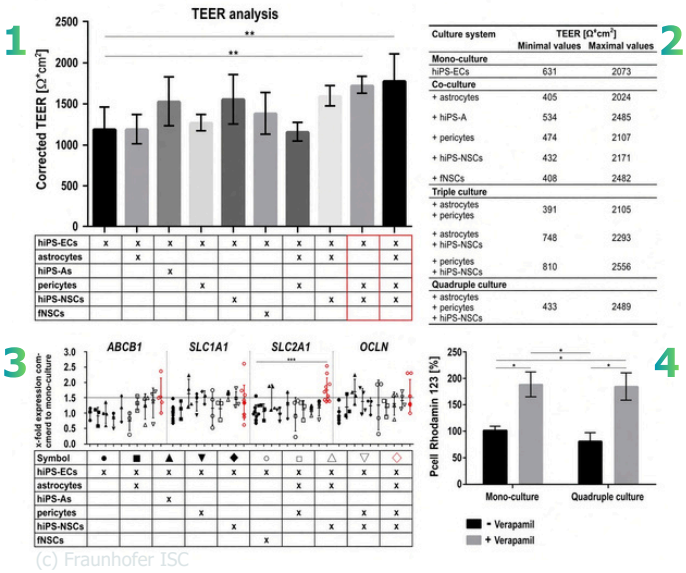
Disease-specific testing
Adaptable to diseases such as Alzheimer's and Parkinson's, supporting human-relevant studies of BBB dysfunction and drug response.

Functional neuronal readouts
MEA technology enables online label-free monitoring of neuronal firing, bursting and synchrony, revealing pharmacological effects or neurotoxicity beyond viability assays.

Earlier, better-informed decisions
Linking BBB transport, brain exposure and neuronal response helps identify promising compounds, explore mechanisms and reduce development risk earlier.



Setup of the blood-brain barrier (BBB) transwell model for analytical substance testing.



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Results

- In vivo-like TEER up to 2500 Ω*cm2 [1,2]
- Strong upregulation of typical BBB genes [3]
- Complex in vivo-like TJ network
- Drug permeability tests with reference substances and infection studies with human pathogens confirmed the predictivity [4]

Available preclinical testing

- Brain-side drug concentration
- Altered transporter activity
- Disease-associated vascular phenotypes
- Abnormal interaction with astrocytes/pericytes
- Patient/genotype-specific drug response
- BBB + PBPK/IVIVE + human exposure data

Custom made test

- Disease-specific BBB models for pre-clinical drug and substance testing
- Assessment of bioavailability
- Assessment of neuro- and cytotoxicity
- Infection studies with human specific pathogen

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Gastrointestinal Tract

Go beyond Caco-2
Bring human intestinal biology into drug development

Caco-2 cells remain a valuable, standardized model for intestinal permeability, and their use is recognized in ICH M9. However, their limited cellular diversity, transporter and metabolic differences, and lack of donor- or disease-specific biology can restrict prediction of human absorption, metabolism and GI toxicity.

Makby portfolio combines Caco-2, primary intestinal organoid and primary-cell Transwell models with immune, endothelial and enteric neural co-cultures, providing a tiered approach to preclinical drug testing.

More predictive assessment of oral drug disposition
Evaluate permeability, transport and intestinal metabolism in models designed to better reflect human intestinal biology.

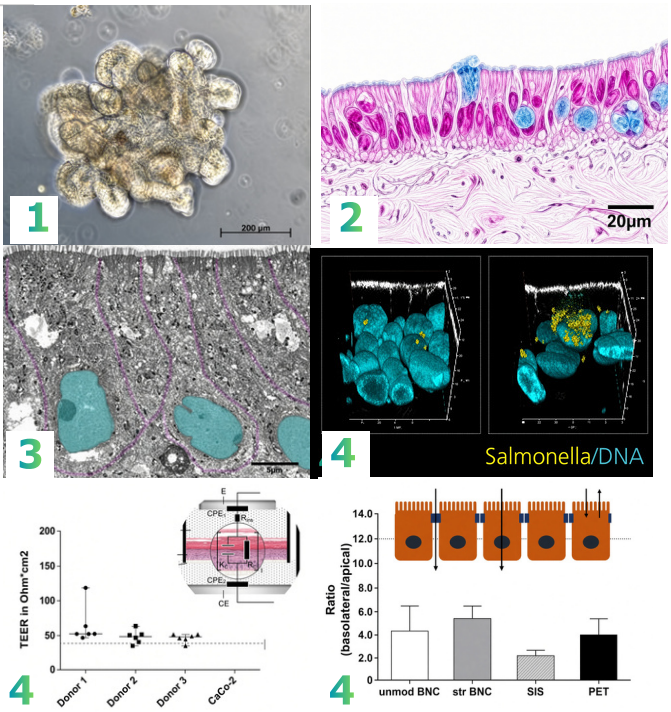
Beyond permeability: transport and metabolism
Characterize active uptake and efflux mechanisms together with intestinal metabolic activity, providing mechanistic insight into why a compound may show limited or variable oral exposure.

Quantitative barrier-function assessment
Combine permeability measurements with TEER, paracellular marker flux and cellular integrity endpoints to distinguish reduced transport from genuine barrier damage.

Mechanistic GI toxicity assessment
Identify epithelial injury, barrier disruption and cellular responses in human intestinal models, providing information beyond conventional viability assays.

Intestinal segment and donor specificity
Human intestinal models can retain characteristics associated with the donor and anatomical region of origin, enabling investigation of inter-individual and regional differences in drug response.

Multicellular intestinal biology
Co-culture with immune, endothelial or enteric neural cells enables investigation of epithelial–immune, epithelial–vascular and gut–neural interactions that cannot be captured by conventional epithelial monocultures.



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Available NAMs models

- Caco-2 cell-based models
- Primary organoid models (ms, hu) [1]
- Primary cell Transwell®-like models (ms, hu) [2]
- Primary intestinal co-culture models (e.g. immune/endothelial/enteric neural cells)

Available preclinical testing

- Histomorphometric and ultrastructural analyses [3]
- Gut absorption, permeability, bioavailability and metabolism (e.g. drugs, nutrients, nanoparticles, pathogens) [4]
- Custom made test procedures depending on the client's needs

Applications

- Drug absorption and transport
- Intestinal metabolism
- Barrier integrity and function
- Drug-induced toxicity
- Disease-specific responses in human-relevant model systems

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3D Immuno Oncology

Human tumor–microenvironment models for immunotherapy efficacy, resistance, mechanism and combination selection.

Conventional preclinical models often fail to reproduce the complexity of the human tumor microenvironment (TME), limiting their ability to predict responses to immuno-oncology therapies. Drug efficacy depends not only on tumor-cell activity, but also on immune activation and infiltration, stromal interactions, vascular access and treatment resistance.

Makby's 3D immuno-oncology NAM platform integrates tumor models with key components of the human TME to provide a more physiologically relevant and mechanistic assessment of drug response.

Disease-relevant tumor diversity
3D architecture and interactions that better reflect solid tumors than 2D cultures. Models are available for melanoma, lung adenocarcinoma, colon and breast cancer, enabling disease-specific studies.

Functional immuno-oncology testing
Integration of immune cells enables assessment of immune activation, tumor-cell killing and immune-mediated pharmacological responses.

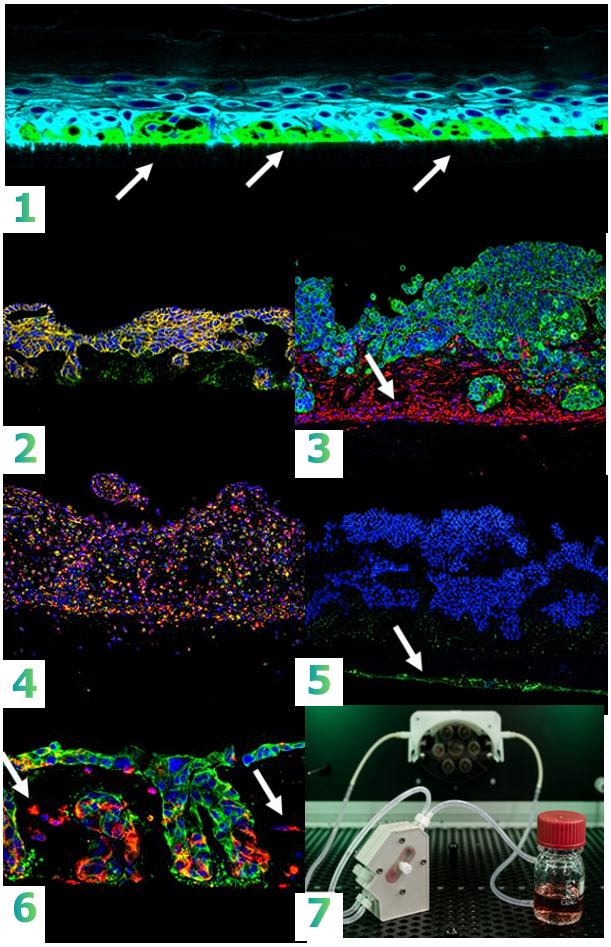
TME modeling
Addition of fibroblasts and endothelial cells allows investigation of how the stromal and vascular compartments influence drug response, tumor growth, immune infiltration and therapeutic resistance.

Mechanistic investigation of treatment resistance
Comparing tumor-only and multicellular models can help identify TME-mediated resistance mechanisms and investigate strategies designed to overcome them.

Immune-cell infiltration and tumor penetration
3D architecture and controlled invasion models enable assessment of whether therapeutic immune cells or other treatments can access and penetrate tumor tissue, an important challenge in solid tumors.

Support for advanced therapeutic modalities
The models can be applied to emerging approaches including checkpoint inhibitors, bispecific antibodies, CAR-T/CAR-NK and other cell therapies, targeted treatments and combination strategies.

A flexible, modular platform
The platform is modular and scalable, ranging from tumor-only models to tumor–stroma, tumor–immune, vascularized and complex multicellular systems—allowing model complexity.



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Available NAMs models
- Malignant Melanoma [1]
- Lung adenocarcinoma [2]
- Colon cancer [3]
- Breast cancer [4]

Available preclinical testing
- Tumor growth inhibition
- Cytostatic activity
- Checkpoint inhibitor response
- Drug recovery/regrowth
- Treatment sequencing

Modifications of tumor models:
Addition of
  - Fibroblasts [3]
  - Endothelial cells [5]
  - Immune cells
- Induction of invasion across the basal membrane [6]
- Enhanced tumor growth in bioreactors [7]

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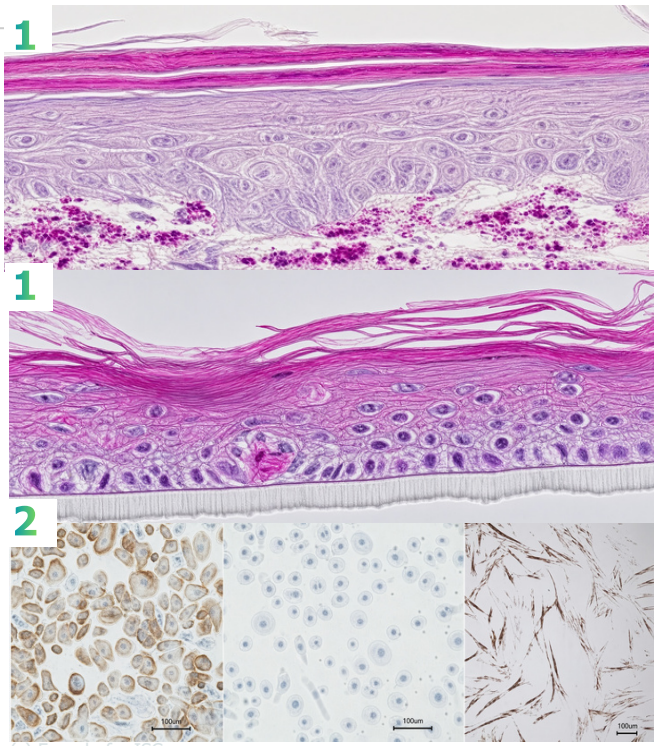
Oral Mucosa

More than a 3D model
Human relevant platform for validating drug–mucosa interactions

Conventional 2D assays enable initial cytotoxicity and mechanistic screening but fail to reproduce tissue architecture, barrier function and cell–cell interactions. Animal models offer greater biological complexity, yet species-specific differences can limit their translational relevance to human oral drug development.

By combining reconstructed oral mucosal models with advanced co-culture and disease-specific systems, the platform enables researchers to generate actionable data earlier in preclinical development.



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Assessment of local mucosal safety
Measure epithelial viability, barrier integrity, tissue damage and inflammatory responses following acute or repeated exposure to drug candidates, formulations or delivery systems.

Transmucosal drug delivery
Quantitatively characterize drug permeation across oral mucosa, including permeability, flux, lag time and tissue retention, supporting the development of buccal and sublingual delivery strategies.

Delivery–safety relationship
Evaluate drug transport and mucosal toxicity in the same experimental system, providing a more informative assessment of the therapeutic window than permeability or cytotoxicity measurements alone.

Mechanistic disease modelling
Model relevant oral pathologies—including mucositis, infection and inflammatory diseases—to investigate disease mechanisms and evaluate potential therapeutic interventions.

Multicellular interactions
Co-culture approaches incorporating epithelial, stromal, immune or microbial components enable investigation of complex tissue responses that cannot be captured by single-cell systems.

Oral oncology applications
Patient-derived oral squamous cell carcinoma models can support drug-response studies and, when paired with normal oral mucosa, enable investigation of tumour efficacy versus normal-tissue toxicity.

Available NAMs models
- Epidermal models [1]
- Co-culture models
- Composed of primary cells or cell lines [2]

Available preclinical testing
- Biocompatibility and oral health care product testing
- Drug delivery studies
- Oral disease modeling

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Eye

From ocular delivery to retinal response Human-relevant platform across the eye

For researchers developing ophthalmic drugs, formulations and advanced therapies, there is a growing need for human-relevant, reproducible and mechanistically informative models that can support candidate selection.

Makby human-relevant ocular NAM platform provides a portfolio of complementary models covering the anterior and posterior eye, including corneal epithelial, hemi-cornea, ex vivo cornea, conjunctival and retinal pigment epithelium (RPE) models.The platform provides a stepwise approach to ocular drug development, allowing researchers to investigate safety, exposure and biological activity in increasingly complex models and generate mechanistic data to support go/no-go decisions.

Physiological tissue architecture
3D corneal, conjunctival and RPE models reproduce key aspects of tissue organization, differentiation and barrier function that are not captured by conventional 2D cultures.

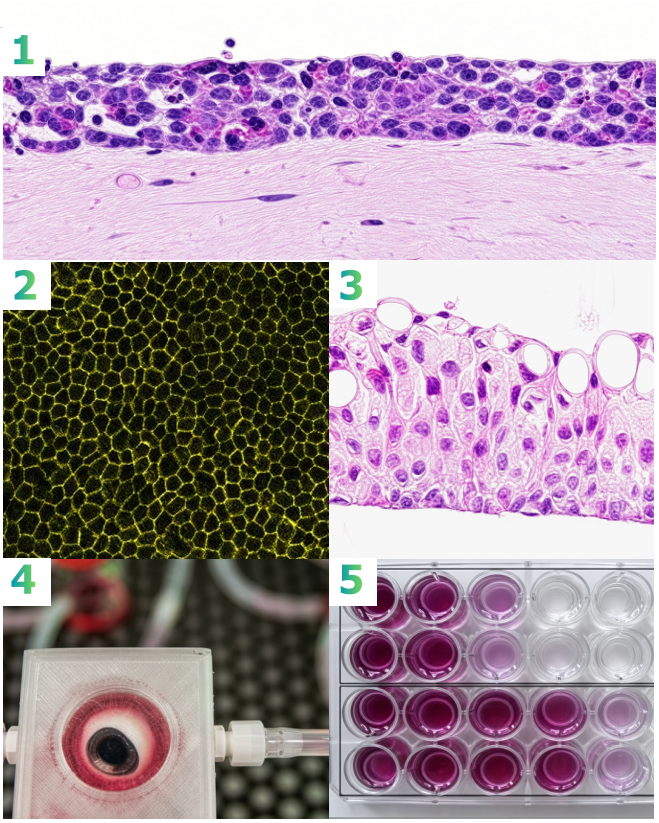
Ocular drug delivery assessment
Quantify drug permeability, penetration, tissue retention and formulation performance to understand whether a candidate can reach its intended ocular site of action.

Safety and tolerability
Assess epithelial injury, barrier disruption, inflammation and recovery following acute or repeated exposure, providing a more comprehensive view of ocular tolerability than simple cell viability assays.

Disease-relevant pharmacology
Model clinically relevant processes such as dry-eye-associated inflammation, corneal injury, infection and RPE dysfunction to investigate mechanism of action and treatment response in human-relevant systems.

Wound-healing and tissue recovery
Measure epithelial repair and barrier restoration following controlled injury, supporting the development of regenerative, protective and anti-inflammatory therapies.
Mechanistic, multiparametric readoutsCombine viability, barrier integrity, permeability, inflammatory biomarkers, tissue morphology, drug penetration and functional responses to generate richer datasets than conventional endpoint assays.

Fit-for-purpose testing
Models and endpoints can be selected according to the specific development question—from standardized ocular safety testing to customized disease, delivery and efficacy studies.



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Available NAMs models
- Cornea epithelial model
- Hemi Cornea model [1]
- Retinal pigment epithelium model [2]
- Ex vivo Cornea model [3]
- Conjunctiva model [4]

Available preclinical testing
- Eye irritation [5]
- Drug penetration and exposure
- Formulation screening
- Inflammation studies

Applications
- Wound healing
- Infection studies
- Compound testing
- Custom made test procedures depending on the client's needs

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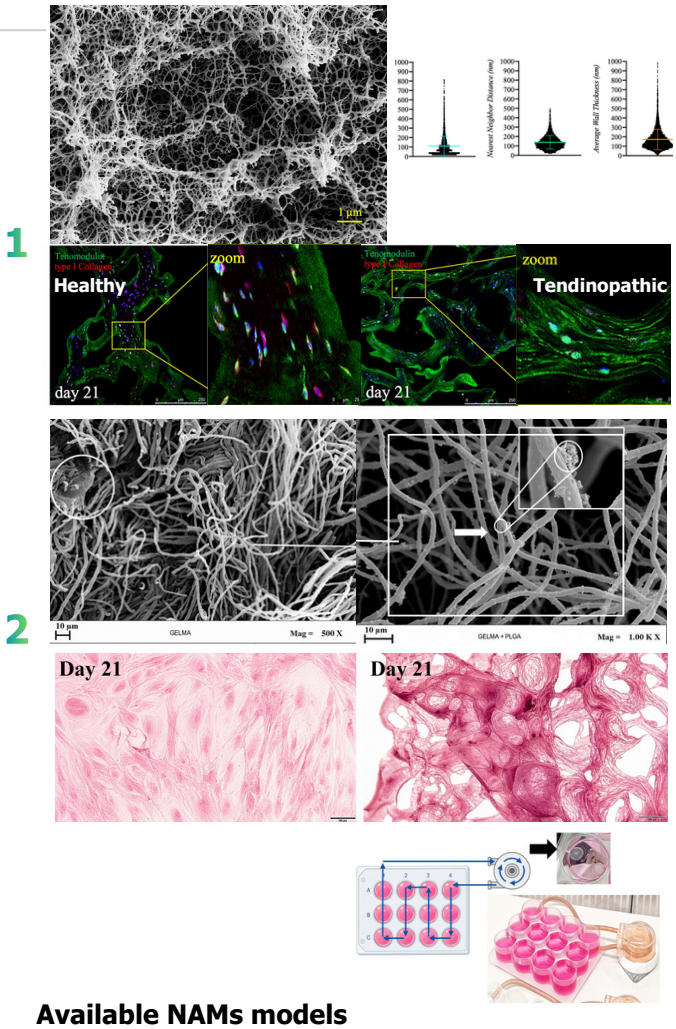
Tendon

From inflammation to matrix remodeling See how your drug changes the tendon

Conventional 2D assays enable initial cytotoxicity and mechanistic screening but fail to reproduce tissue architecture, barrier function and cell–cell interactions. Animal models offer greater biological complexity, yet species-specific differences can limit their translational relevance to human oral drug development.

Makby NAM Tendon enables simultaneous assessment of inflammation, tenogenesis, collagen remodeling, matrix organization and tissue mechanics, while also supporting the evaluation of local drug-delivery systems and nanomedicines.



3D tissue architecture and matrix remodeling
Recreates a structured extracellular-matrix environment in which collagen production, remodeling and pathological changes can be investigated at the tissue level.

Disease-relevant phenotypes
Supports healthy and diseased/inflammatory conditions, enabling the study of tendinopathy, chronic inflammation and pathological fibrosis as well as therapeutic recovery.

Multiparametric assessment of efficacy
Combines tenogenic markers (SCX, TNMD), matrix markers (COL1A1, COL3A1), collagen organization and inflammatory biomarkers (IL-6, IL-8) to provide a comprehensive characterization of drug response.

Local drug and nanomedicine testing
3D bioprinted models incorporating PLGA nanoparticles and growth-factor delivery systems enable investigation of local therapeutic delivery, controlled release and tissue responses within the target tissue.

Tendon regeneration and repair
Supports evaluation of compounds and biomaterials designed to promote tenogenesis, matrix restoration and tissue regeneration following tendon injury or degeneration.

Tendon–bone interface modeling
Bioprinted GelMA-based systems enable investigation of enthesis biology, osteoinduction, matrix mineralization and tissue-interface regeneration, relevant to tendon-to-bone repair strategies.

Available NAMs models

- Perfused 3D Fibrin Hydrogel Model with Healthy vs. Tendinopathic hTSPCs [1]
- 3D Bioprinted ColMA + PLGA Nanoparticles for tendinopathic fibrosis & chronic inflammation
- A 3D bioprinted Gelatin Methacryloyl (GelMA) scaffold incorporating microfluidic-fabricated nanocarriers cultured under dynamic perfusion to model tendon-to-bone enthesis differentiation and matrix calcification [2].

Available preclinical testing

- Anti-inflammatory drug efficacy
- Tendinopathy disease-modifying activity
- Tenogenic differentiation / tendon regeneration
- Anti-fibrotic drug testing
- Nanomedicine screening

BUILD A STRONGER WEIGHT-OF-EVIDENCE PRECLINICAL STRATEGY WITH OUR TISSUE ENGINEERING TEAM

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