ImmUniverse

Better control and treatment of immune-mediated diseases by exploring
the universe of microenvironment imposed tissue signatures and their correlates in liquid biopsies

Webinar for patient communities

Presentation of key findings on immune-mediated conditions, including cross-disease insights and results on atopic eczema and inflammatory bowel disease (IBD)

13 May 2026, 9:00-10:30 CEST

ImmUniverse has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No. 853995. The JU received support from the European Union's Horizon 2020 research and innovation programme and EFPIA. www.imi.europa.eu

Agenda

1. Welcome and introduction
2. ImmUniverse: project overview, objectives, approach, cross-disease results
3. Key findings and outputs on atopic dermatitis
4. Key findings and outputs on inflammatory bowel disease
5. Q&A
6. Closing

Welcome and introduction

Yasemin Zeisl, European Patients' Forum (EPF)

Welcome

Housekeeping

- This session will be **recorded and shared publicly** on the ImmUniverse project website

Webinar goals

- **Inform you** about key project results and takeaways
- **Offer you space to ask** our experts questions
- **Provide today's recording and materials** so you can go back to them anytime and share them with your community

Our speakers & moderators

- Stefania Vetrano, Associate Professor, Humanitas University
- Robert Häsler, Professor of Systems Medicine in Dermatology, Christian-Albrechts-University Kiel
- Florian Tran, Professor of Pathophysiology of Chronic Inflammation, Christian-Albrechts-University Kiel
- Yasemin Zeisl, Project Coordinator, European Patients' Forum (EPF)

ImmUniverse: project overview, objectives, approach, cross-disease results

Stefania Vetrano, Humanitas University, ImmUniverse Coordinator

ImmUniverse Key Facts

Start Date
1 January 2020

Duration
6.5 years (incl 18 months project extension)

Budget
31 Mio. (50% IHI funding, 50% EFPIA funding)

29 Partners
10 Countries

What are immune-mediated inflammatory diseases (IMIDs)?

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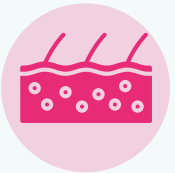
IMIDs are a group of long-lasting conditions caused by an **imbalanced immune response**.

This imbalance causes ongoing inflammation that can damage tissues and affect how organs work.

They can affect many parts of the body, including:

Gut
e.g. Inflammatory bowel disease (ulcerative colitis, Crohn's disease)

Joints
e.g. Rheumatoid arthritis



Skin
e.g. Psoriasis, atopic dermatitis

These conditions can lead to **significant symptoms**, reduced quality of life, more complications, and even a **higher risk of serious health problems**.

The challenge today

We don't have reliable **biomarkers** (biological signals) that can tell us how the disease will develop or how a person will respond to treatment.

This makes it very hard to **predict** the course of the disease and to choose the **right treatment** for the right person at the right time.

As a result, many patients need to try several treatments, and a large proportion still **do not respond well enough** to available options.

IMIDs are complex and affect everyone differently. ***We need better ways to understand, predict and treat these diseases – for each individual.***

Why a project on Immune-mediated inflammatory diseases?

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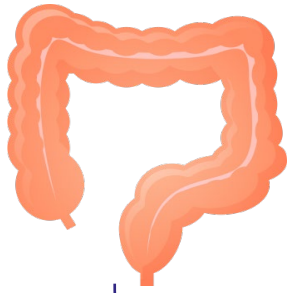
Immune-mediated inflammatory diseases (IMIDs) are debilitating conditions characterized by dysregulated immune responses leading to destructive chronic inflammation

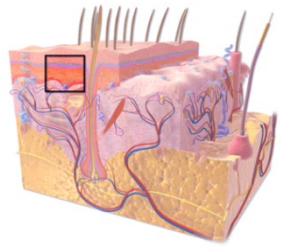
Ulcerative colitis (UC)

GUT



Atopic dermatitis (AD)

SKIN



UNMET NEED

Lack of mechanistic understanding of pathogenesis and absence of (non-biopsy) biomarkers to predict disease progression and clinical/therapy outcome.

Why do symptoms vary from patient to patient?

In immune-mediated diseases like UC and AD, many factors influence how the disease shows up in each person.

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No two patients are the same
Each person's body and disease are unique.

Many factors can influence symptoms

Genetics
Our genes influence how our immune system works.

Immune system activity
The type and level of immune response can differ.

Tissue / skin or gut barrier
Barrier strength and local inflammation can vary.

Microbiome
The community of bacteria in our gut and on our skin differs between people.

Environment & lifestyle
Diet, stress, pollution, sleep and infections can play a role

Age, sex & hormones
These can influence the immune system and symptoms.

Complex interactions

Different combinations lead to different symptoms

- Different symptoms
- Different severity
- Different impact on daily life

Why do patients react differently to treatment?

Treatments work in different ways, and many factors influence how well they work for each person.

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Treatment works in many steps

Drug is taken → Absorbed and reaches the body → Reaches its target → Helps reduce inflammation

Many factors can influence how a treatment works

Genetics
Affects how we process drugs and how our immune system responds.

Disease subtype & activity
Different underlying mechanisms can respond differently.

Microbiome
Can affect treatment metabolism and immune effects.

Immunogenicity
The body may create antibodies against the drug, reducing its effect.

Lifestyle & other health conditions
Weight, diet, stress, smoking and other conditions can influence results.

Adherence
Taking the medicine as prescribed is essential for it to work.

All these factors together influence the outcome

Different responses to the same treatment

Responds well | Responds partly | No significant response | Side effects / Cannot take

Understanding these differences helps us move towards more personalized treatment for each patient.

By understanding the many reasons behind variability, ImmUniverse aims to predict, personalize and improve care for every patient.

Our approach: combining many pieces of information

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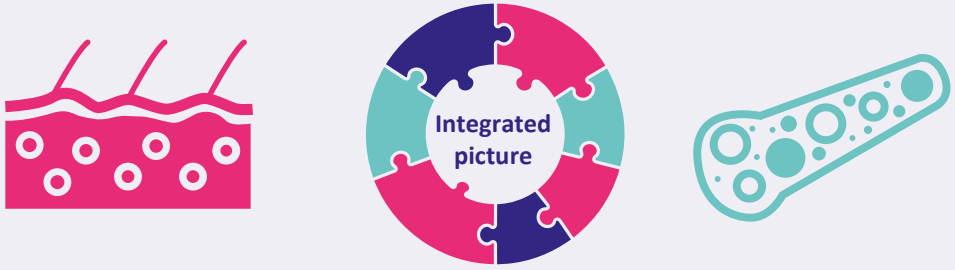
We study two conditions

- Ulcerative colitis (UC)
- Atopic dermatitis (AD)

We bring together many types of data

- Genes (genomics)
- Gene activity (transcriptomics)
- Proteins (proteomics)
- Metabolites (metabolomics)
- Immune cells (immunomics)
- Clinical data

We build a complete (holistic) view of the disease Integrated picture



From tissues (gut and skin) and blood (circulating biomarkers

This leads to better tools for better care

- New molecular tests (biomarkers)
- Better patient stratification (who will benefit from which treatment)
- Monitoring disease severity and progression over time
- Right treatment, right escalation, right time

Our ultimate goal: more personalized care, better outcomes and improved quality of life for patients with UC and AD.

What is new in ImmUniverse?

- Most studies look at one disease → we compare across diseases
- Most look at one data type → we combine many
- Most rely on invasive biopsies → we explore less invasive methods

What will NOT change (yet)

- These are research findings, not yet routine clinical tests
- More validation is needed before use in hospitals

Why this matters to YOU

Today, many patients:

Try several treatments
before finding one that works

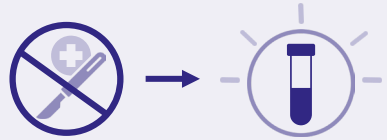
Experience uncertainty
about disease progression

ImmUniverse results aim to:

Predict which treatment will work for you

Detect disease changes earlier

Reduce invasive procedures



Our goal: more personalised care, better outcomes and improved quality of life.

Patients at the heart of ImmUniverse

Patients and patient experts are true partners in our research.

1. Priorities & needs
Patient experts helped set research priorities.

For example in atopic dermatitis (AD): itch over 10 years, flare frequency, quality of life and more.

2. Lay summaries
Patient experts contributed to lay summaries so that results are clear, accurate and easy to understand.

3. Review & feedback
Patients review results and messages to make sure they are clear, balanced and meaningful.

We avoid raising false hopes and focus on realistic, helpful information.

4. Sharing real experiences
Study participants shared their insights about living with the disease and taking part in the clinical study.

5. Outreach & awareness
Patients took part in videos (e.g. dOFM) and interviews to help explain our research and technologies to others.

Your voice helps us do the right research and turn results into better care for everyone.

Together, we make ImmUniverse research more relevant, understandable and impactful.

You shape our research ➡ We generate better knowledge ➡ This leads to better tools and better care ➡ For a better future for all patients

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Patient Webinar:

How Can People Living With Eczema Benefit From Our Research?

Prof. Dr. R. Häsler

2026-05-13

How to find out what really matters?

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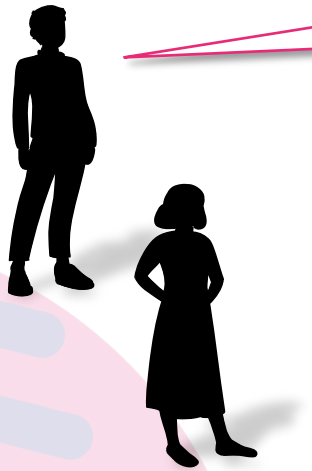
...speak to the right people!



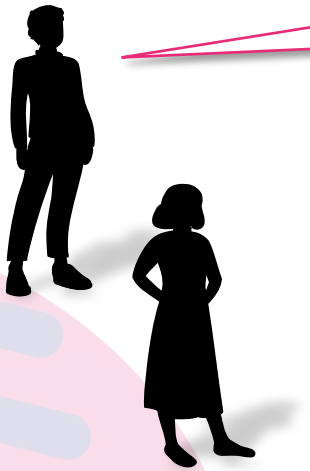
I know what I need!

...and I need it now!

I see room for improvements

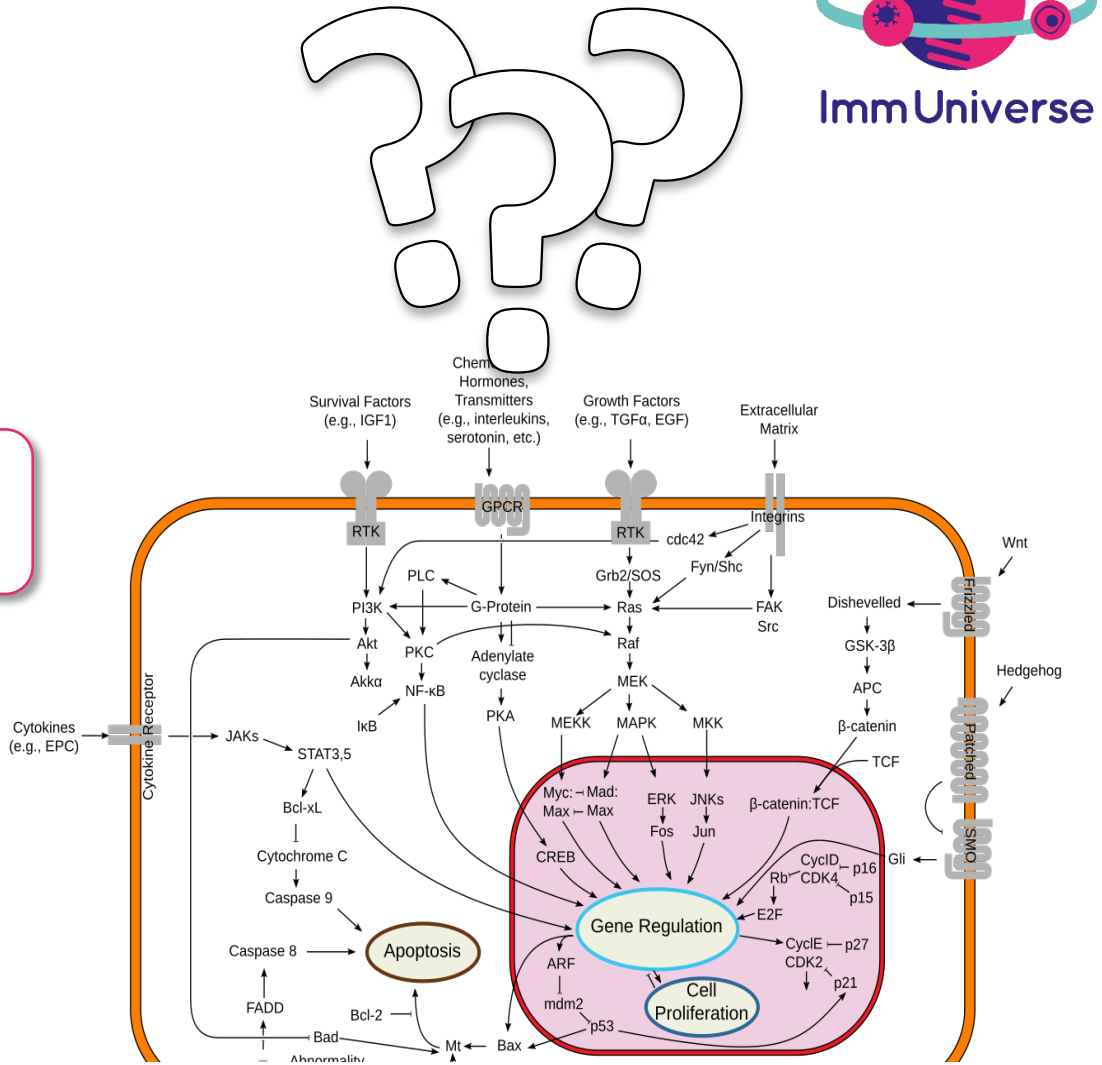
with some help, we can do it

Does basic science help?



we don‘t need fancy pictures...

...we need to improve our quality of life!



Why participate?

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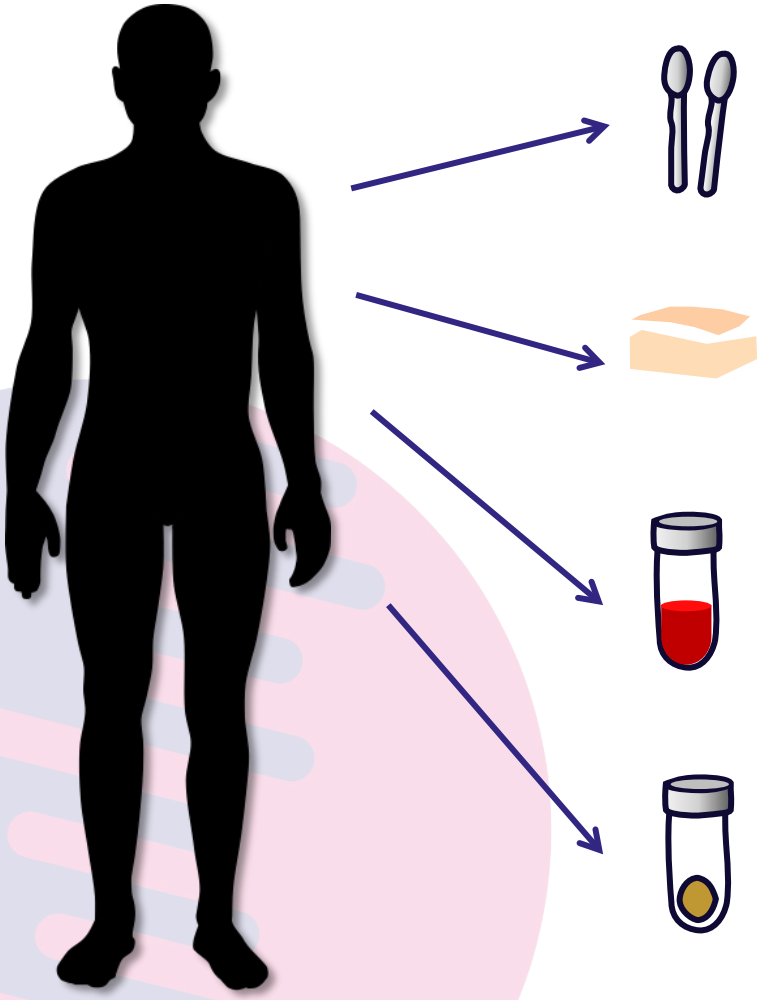
Advantages

- access to state-of-the art treatment, beyond regular care
- close monitoring of eczema course, continuous quality control
- involvement of top experts across Europe – they work for you
- you contribute to science, help you and help others
- psychological advantage: you are being take care of, interaction with experts, safety aspects

Disadvantages

- no guaranteed improvement of symptoms
- time consuming & small steps only

Why so many samples?



cotton swabs	bacteria on the skin	beneficial and non-beneficial bacteria
skin biopsies	direct signals: skin events	gene activities, defense, gene memory, immunity, therapy results, high resolution images
blood samples	indirect signals: for diagnostics	circulating messages of diagnostic value, immune system responses, metabolism
stool samples	bacteria in the digestive tract	effects on overall health, impact of therapy

First results: observed improvements

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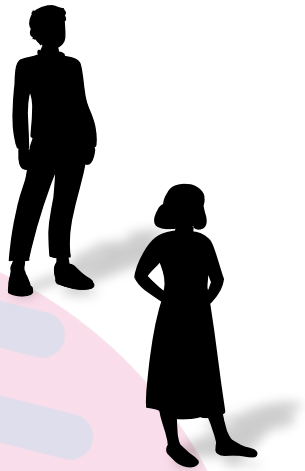
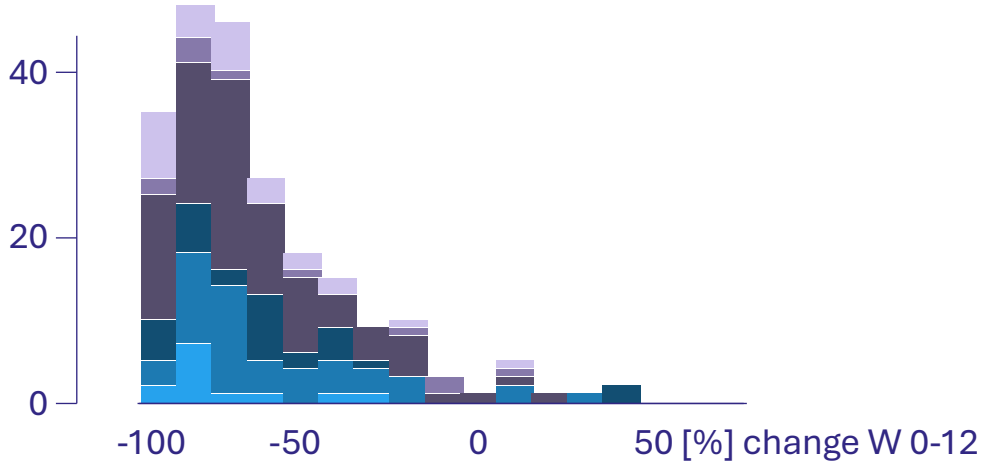
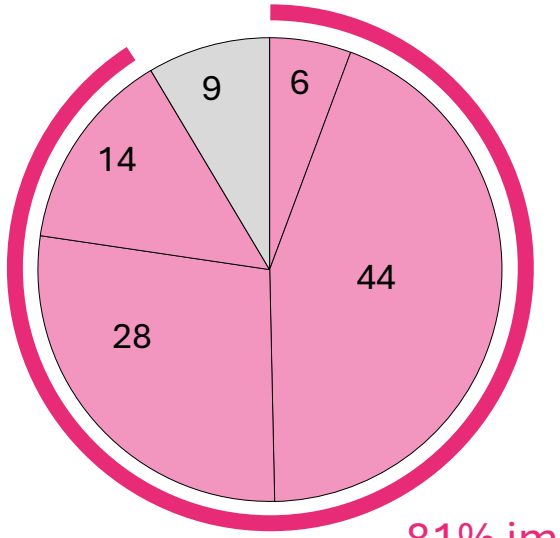


EASI

Eczema Area and Severity Index





81% improve

- Abrocitinib
- Baricitinib
- Dupilumab
- Lebrikizumab
- Tralokinumab
- Upadacitinib

[%]

- Super Responder
- Responder
- Partial Responder
- Low Responder
- Non Responder

First results: what matters for people with eczema?

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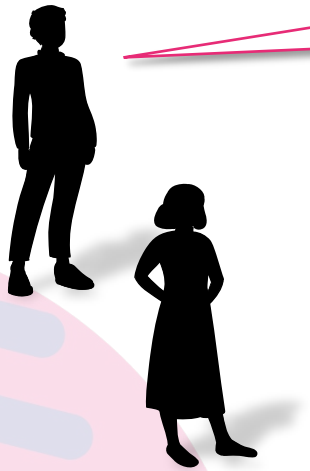
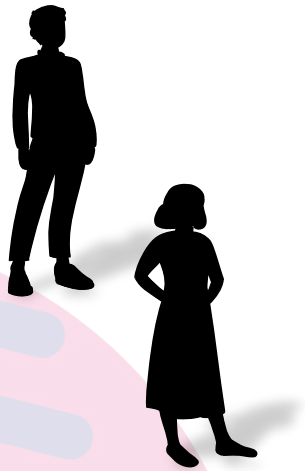


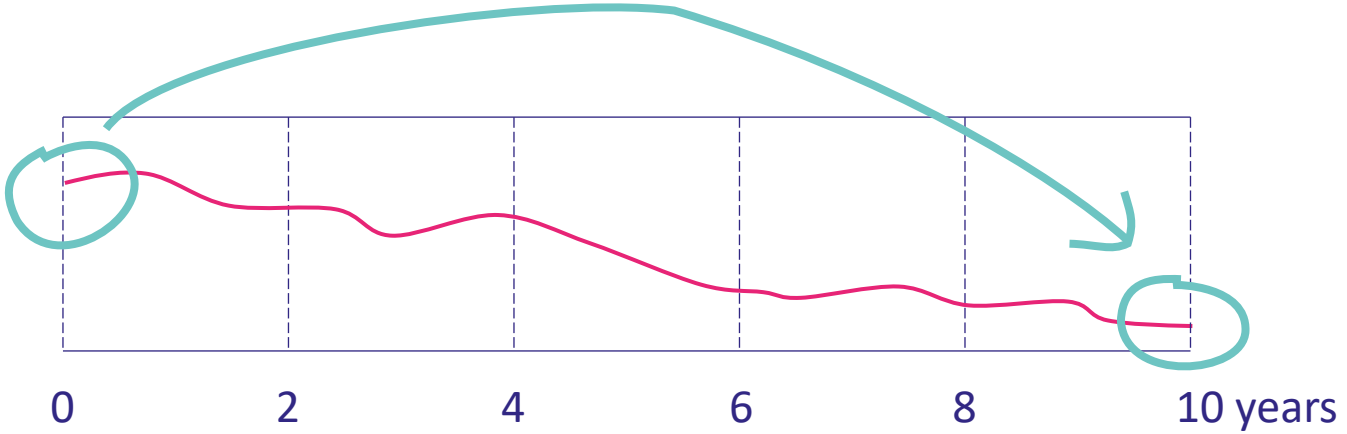
I hate the itching!

I am worried of recurring flares

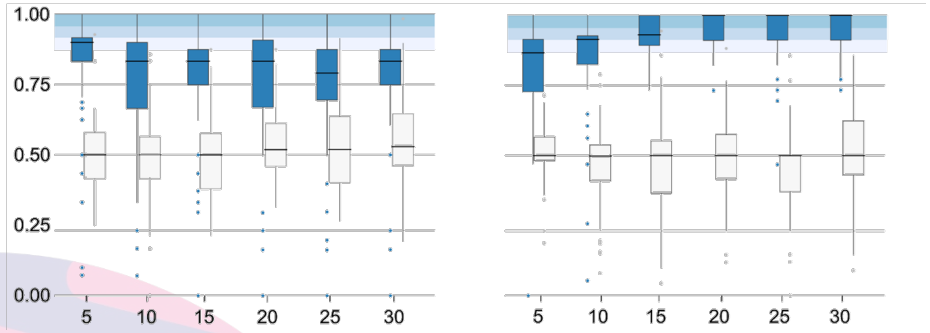
therapy adherence is challenging

Robust prediction: support for long term management

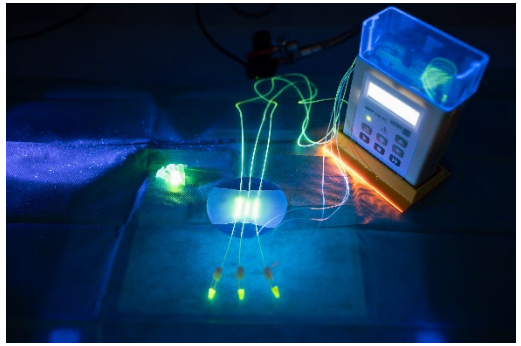




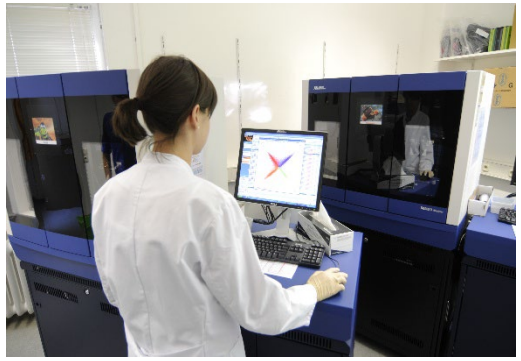
Robust prediction: results on itch



- high quality clinical samples
- state-of-the-art molecular analytics
- bioinformatic analysis



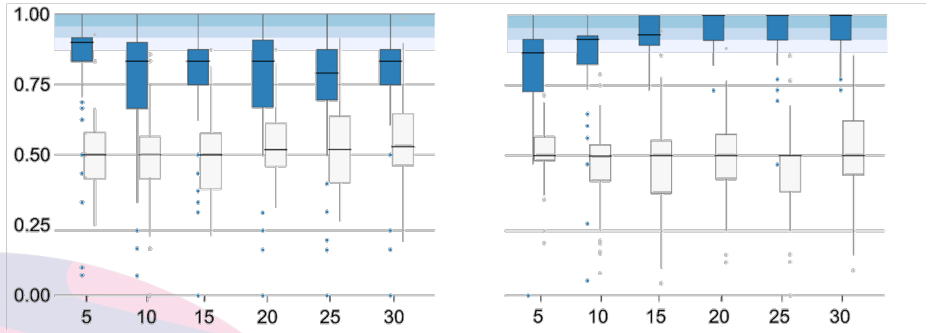
novel skin biosampling

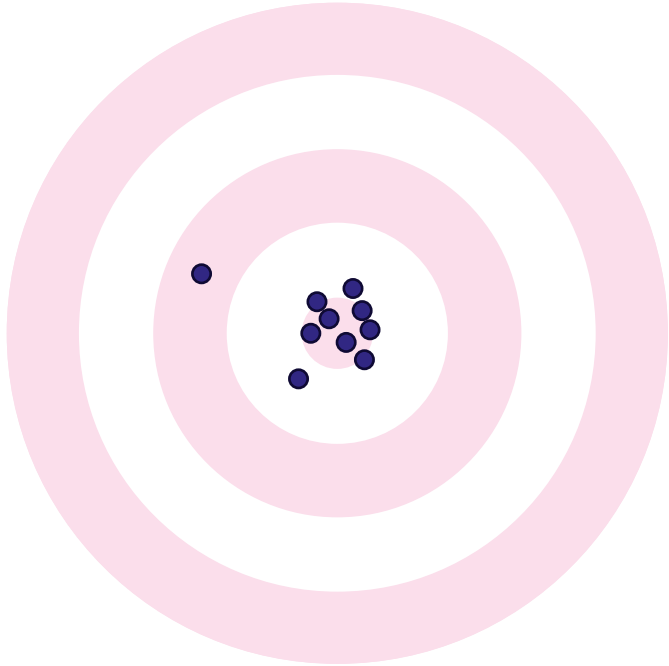


analytical facilities

high performance computing

Robust prediction: results on itch

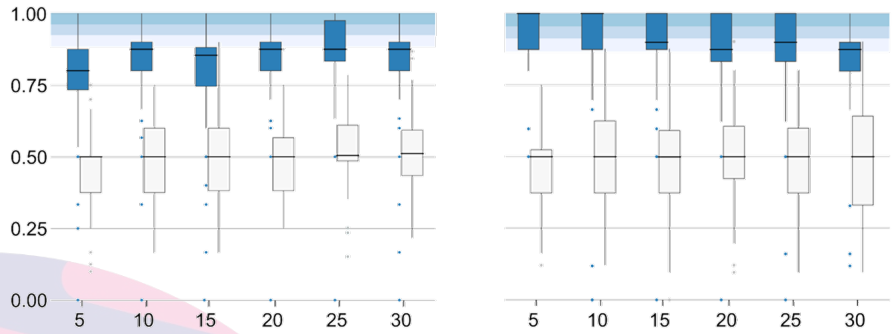


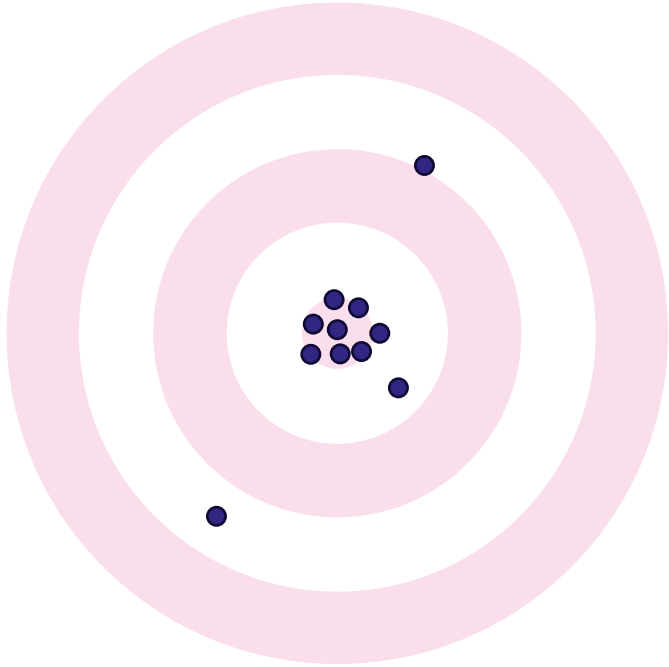


- high quality clinical samples
- state-of-the-art molecular analytics
- bioinformatic analysis

accuracy:
85 – 100 out of 100
itch improvements
correctly predicted
for 10 years

Robust prediction: results on flares





- high quality clinical samples
- state-of-the-art molecular analytics
- bioinformatic analysis

this was three years of analytical work

accuracy:
80 – 95 out of 100
flare improvements
correctly predicted
for 10 years

Other findings #1: involved cells

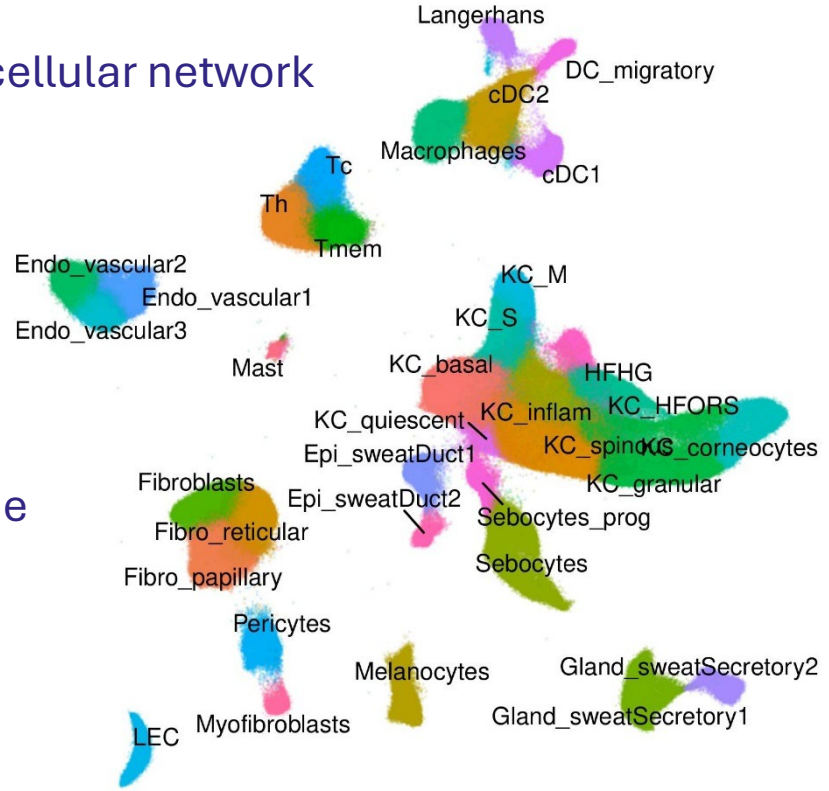
skin biopsy

single cell sequencing

data processing

finalizing the picture

deciphering the cellular network



Other findings #2: molecular patterns

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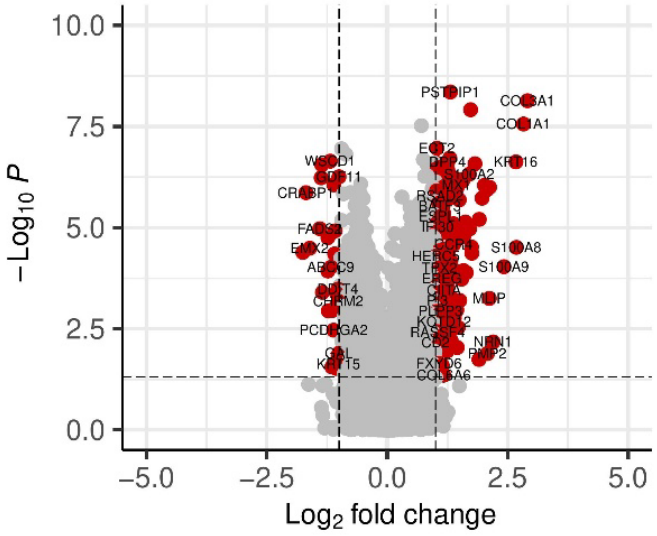
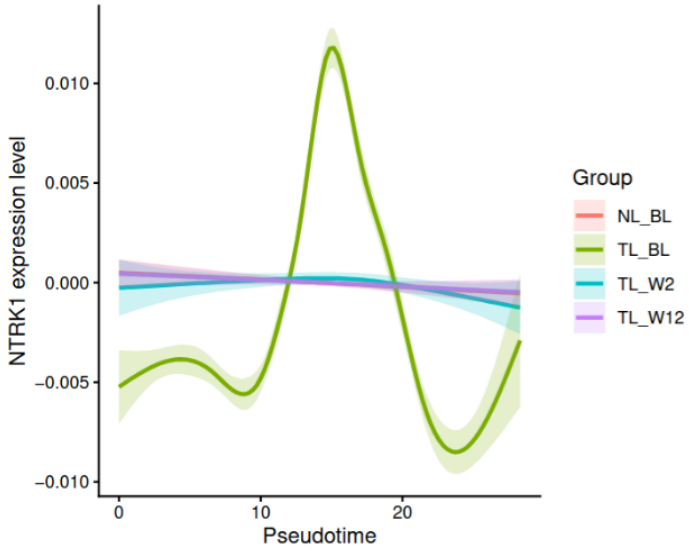
monitoring gene activities
involved in inflammation



monitoring changes,
relevant to therapy response



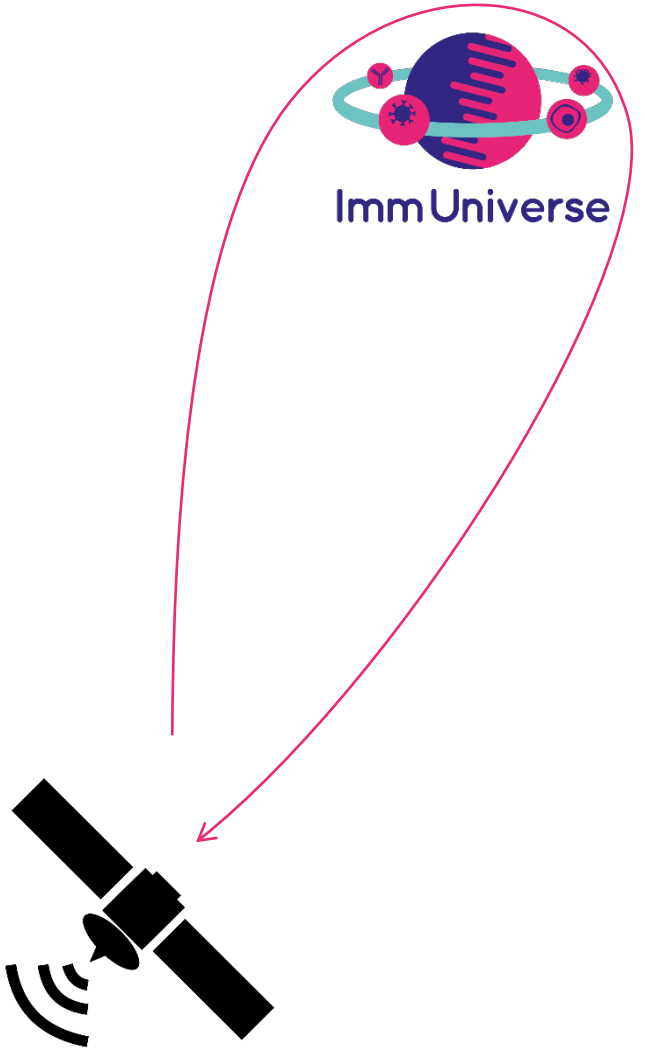
What's next?

short term:

- finalize on-going analysis
- share results with the community

longer term:

- integrate results from different partners
- run in-depth analysis on cellular responses to therapy
- publish predictors of clinical relevance
- embed approaches into clinical routine



How can you contribute in the future?

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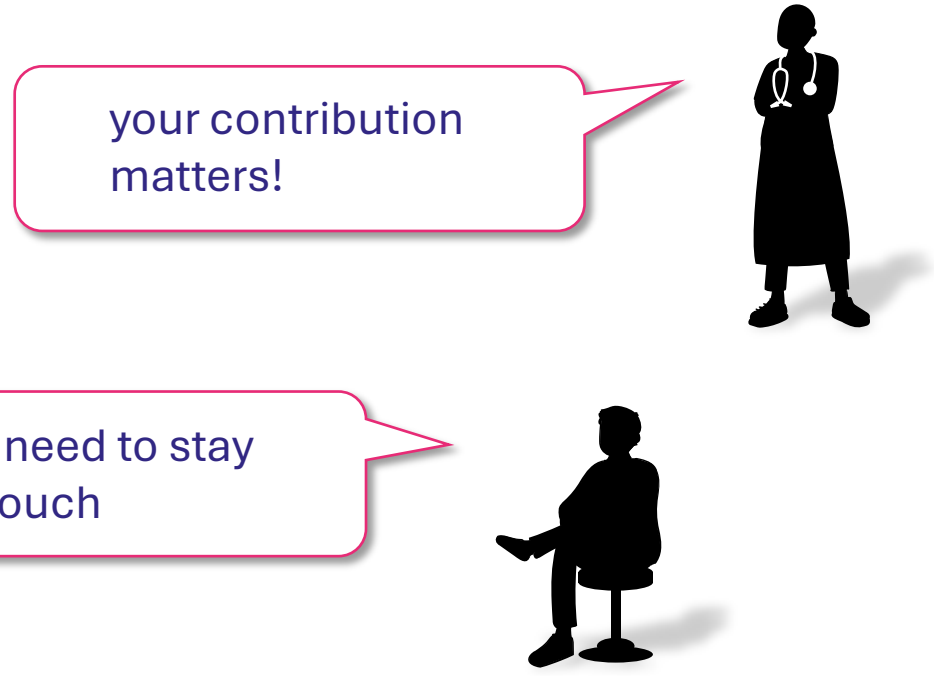
- spread the word
- support activities in both: science and patient organizations
- give feedback about and to scientists
- participate in future studies



Summary: direct benefits

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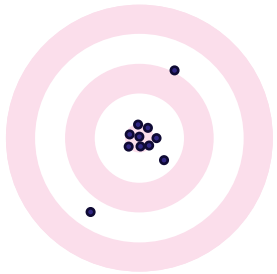
- 3 years of preparation & 6 years of successful studies
- support for individuals with eczema: prediction provides perspectives
- improve long-term disease management
- several ongoing analytical approaches
- raised awareness in the community: enabling new studies



The ImmUniverse team

Key findings and outputs (so far) on inflammatory bowel disease/ulcerative colitis

Florian Tran

for the UC team in ImmUniverse

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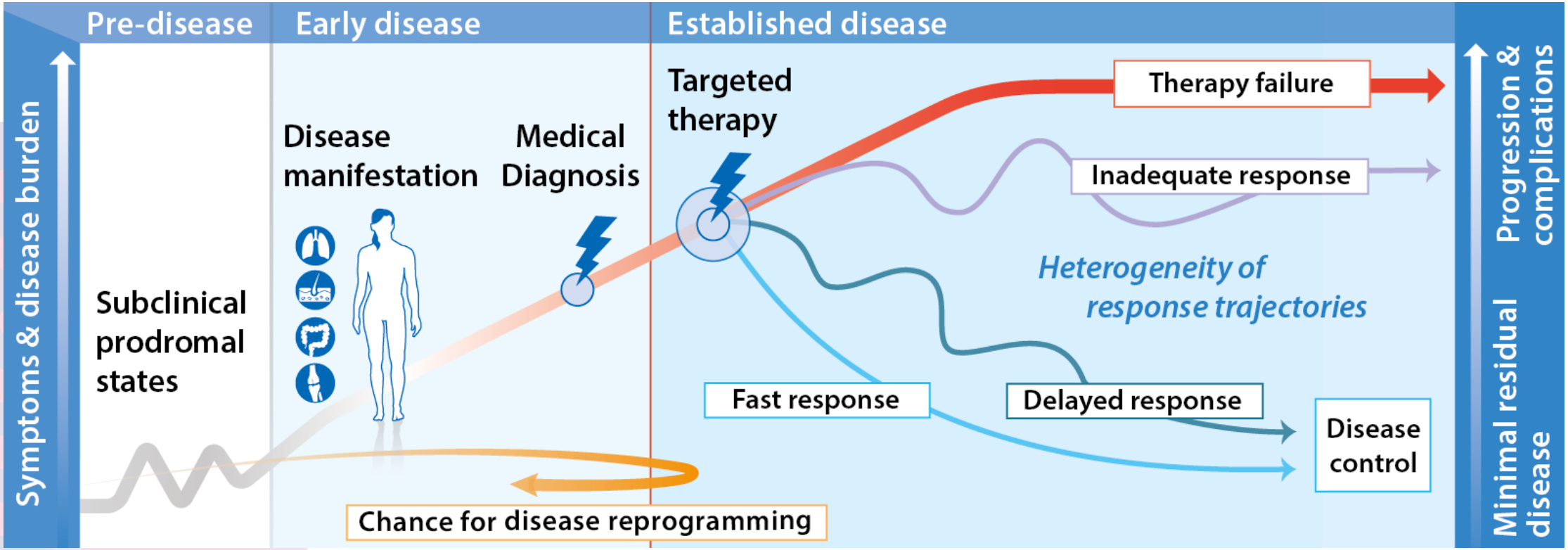
Confidentiality

All information disclosed during this meeting is confidential information and must not be used elsewhere without written consent!

Heterogeneity of inflammatory bowel disease

Heterogeneous **natural histology, site of manifestation, disease trajectory**

Concept figure from:
ExC PMI Renewal Proposal



Identification of shared and unique mechanisms of atopic dermatitis and ulcerative colitis bowel disease patients

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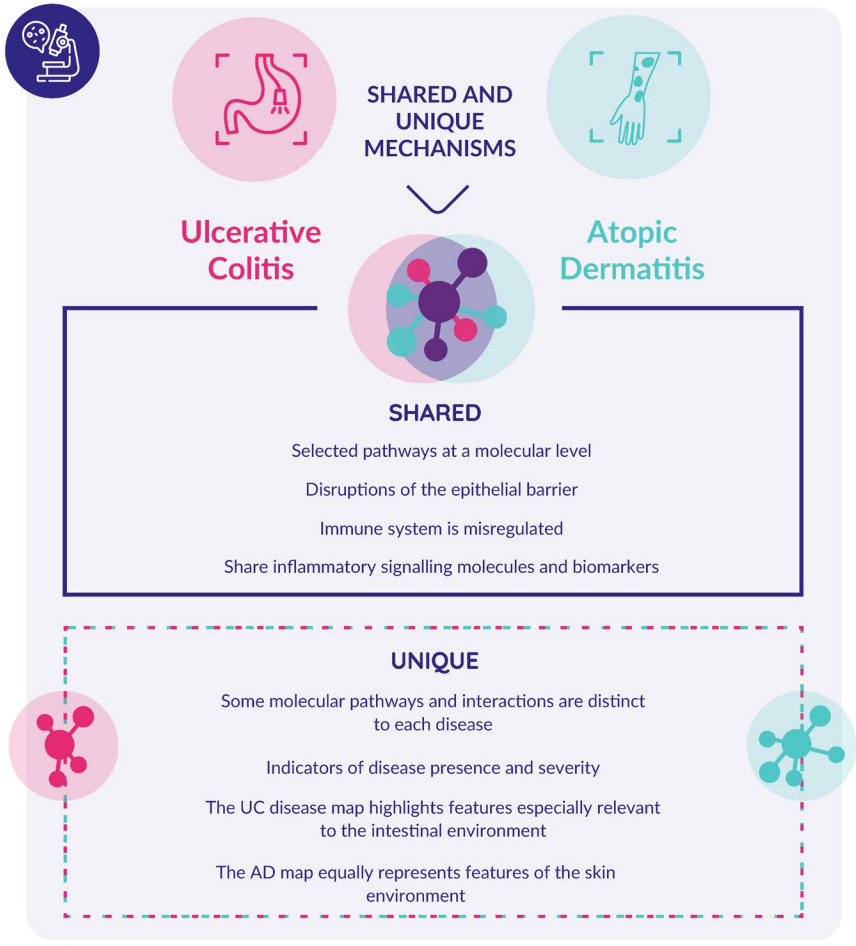
MAP AND COMPARE MOLECULAR PROCESSES BEHIND ULCERATIVE COLITIS (UC) AND ATOPIC DERMATITIS (AD)

to find which mechanisms are common and which are unique

- Disease maps for UC and AD (graphical models showing molecules, genes, proteins)
- Compared maps to identify overlapping pathways and disease-specific ones
- Overlaid omics data and disease-associated genes to see which parts are most relevant to real patients

FINDINGS

- Different diseases (skin vs gut) shareshare hidden biological "wiring"
- Mapping helps organise vast amounts of biomedical knowledge
- A therapy developed for one disease might benefit the other
- Enable precision medicine



Heterogeneity of inflammatory bowel disease

Heterogeneous **natural histology, site of manifestation, disease trajectory**

Concept figure from:
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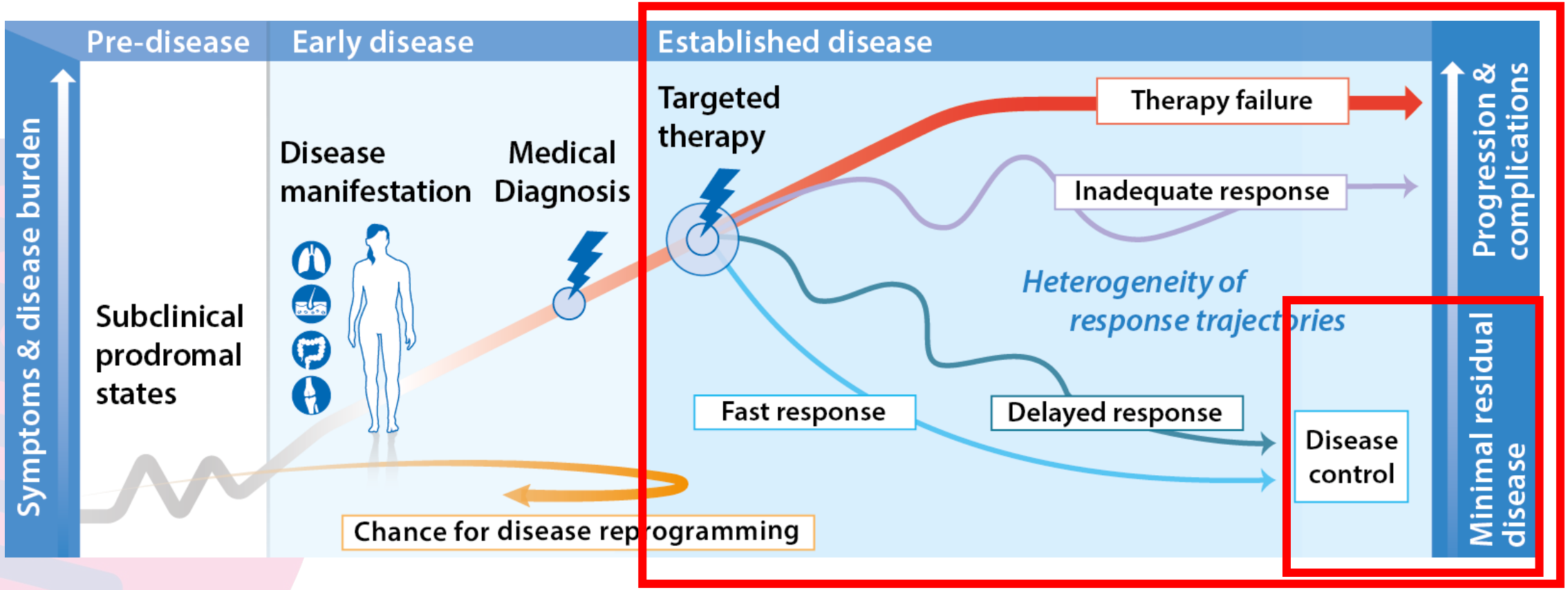
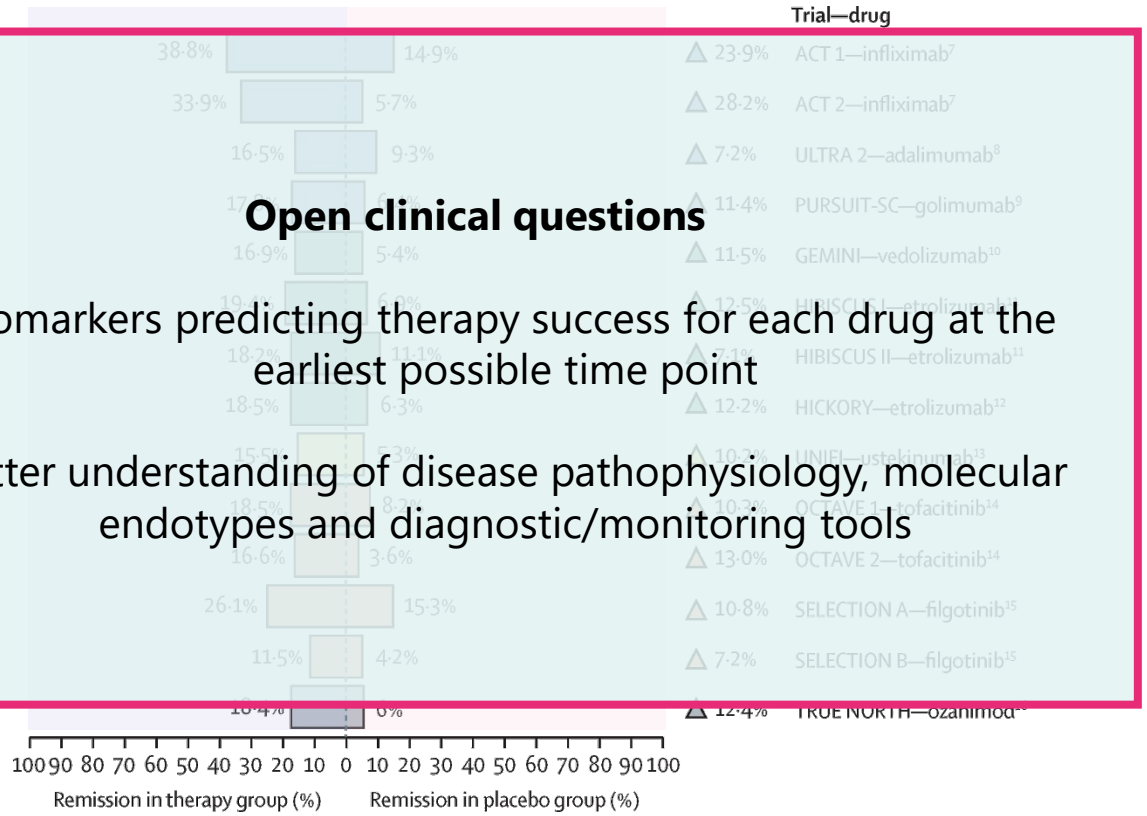


Therapy success in Ulcerative colitis

52 weeks clinical remission rate in trials



Open clinical questions

→ Biomarkers predicting therapy success for each drug at the earliest possible time point

→ Better understanding of disease pathophysiology, molecular endotypes and diagnostic/monitoring tools

Alsoud *et al*, 2021 Lancet Gastroenterol Hepatol

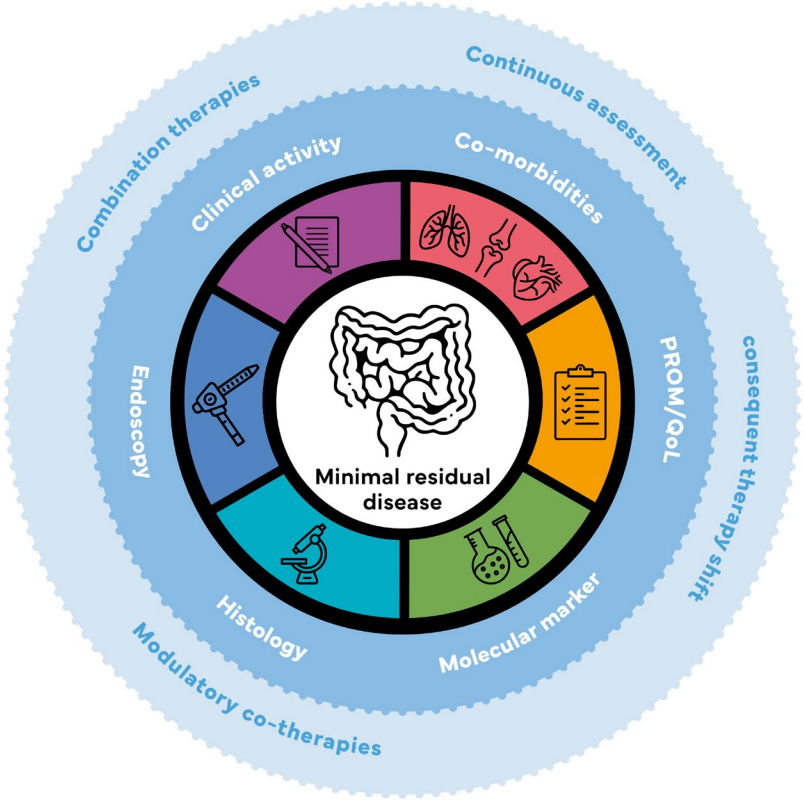
What is the best for our patients?

Definition of **comprehensive disease control: Combination of**

- **Clinical Remisison = No symptoms**
- **Endoscopic Remission = No inflammation in endoscopy**
- **Histological Remisison = No inflammation in intestinal biopsy**
- **Biochemical Normalization = No inflammation in blood and stool**

Future concept might include:

- Quality of life
- Co-morbidities
- Further patient-reported outcomes (fatigue?)



Schreiber, Aden, Tran, Rosenstiel, Gut 2025

Rigorous Longitudinal Tracking: The UKSH Kiel Cohort (2010–2022)

n = 231 Patients
UKSH Kiel

Induction therapy with biologics / JAKi

Week 0 Week 2 Week 6 Week 14 Week 26 Week 52

Top Track: High-Frequency / Non-Invasive

PMCS
CRP
Leucocytes

w0 w2 w6 w14 w26 w52

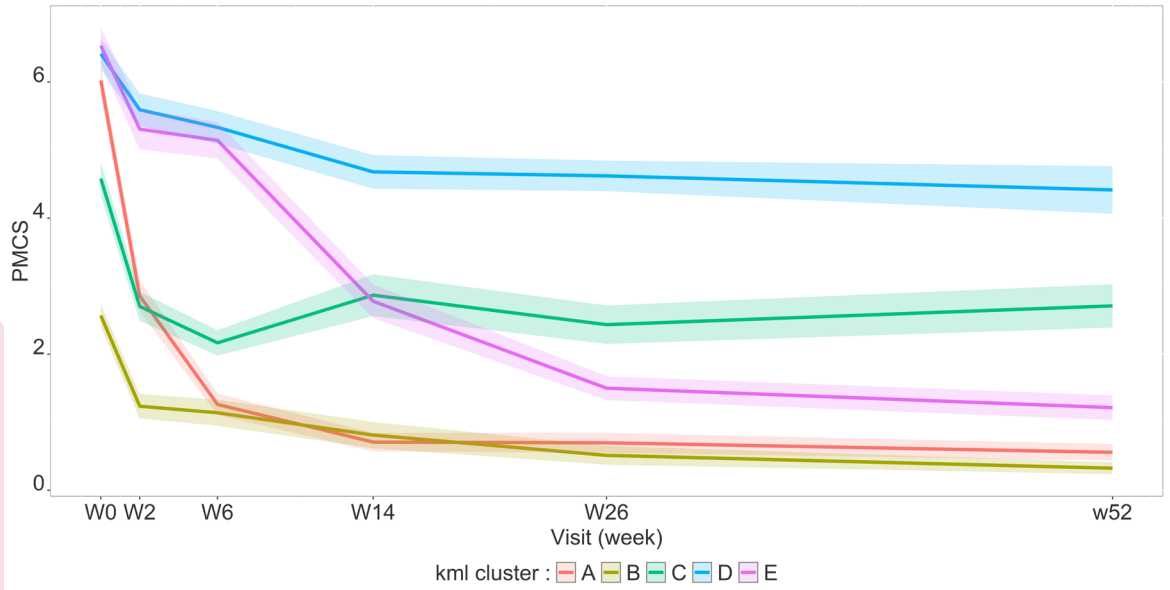
Bottom Track: Milestone / Invasive

eMayo
Nancy Index

w0 w14 w52

W52 outcomes

Comprehensive disease control



0%

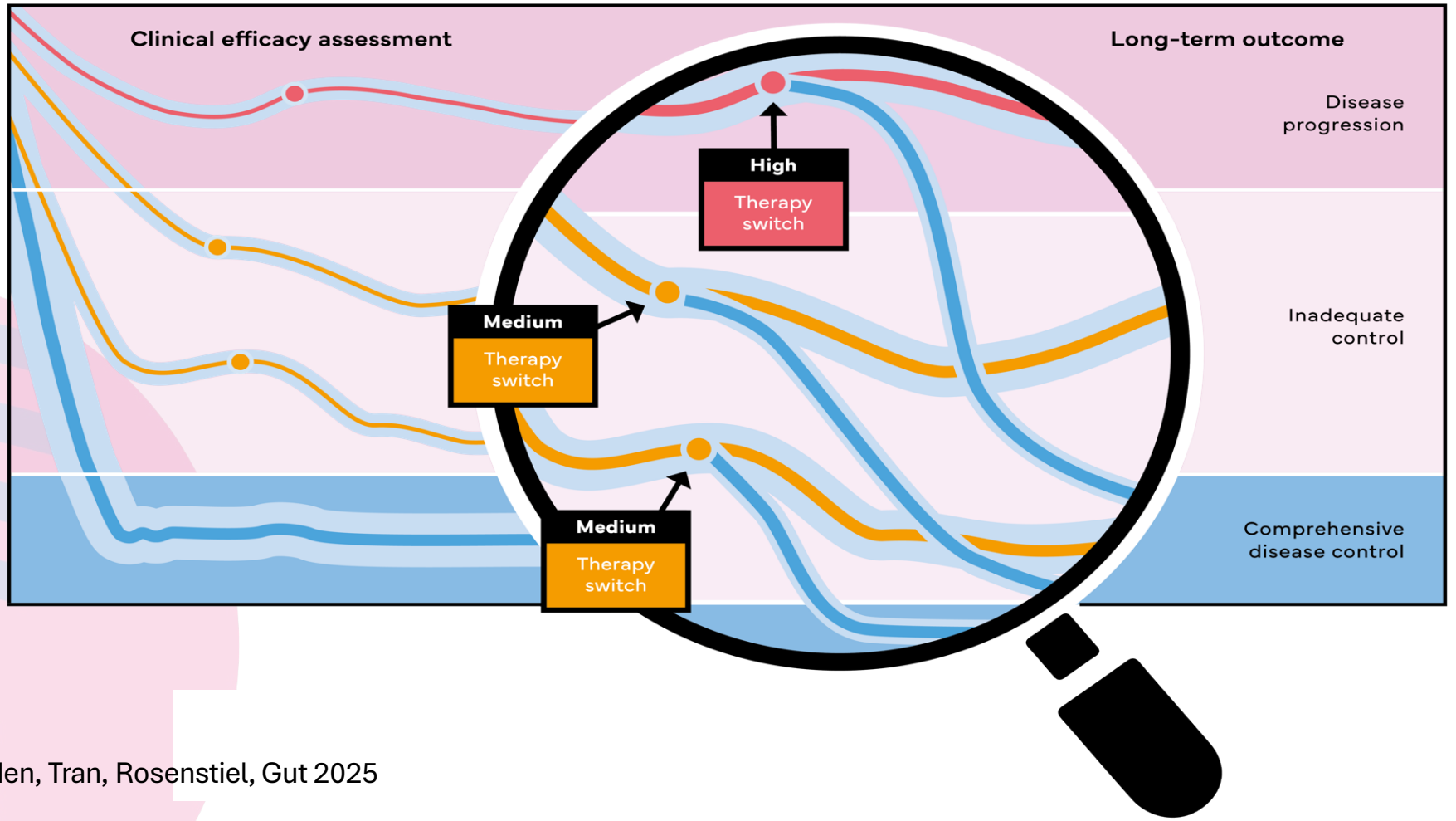
3.7%

22%
31%
50%

Long-term disease control

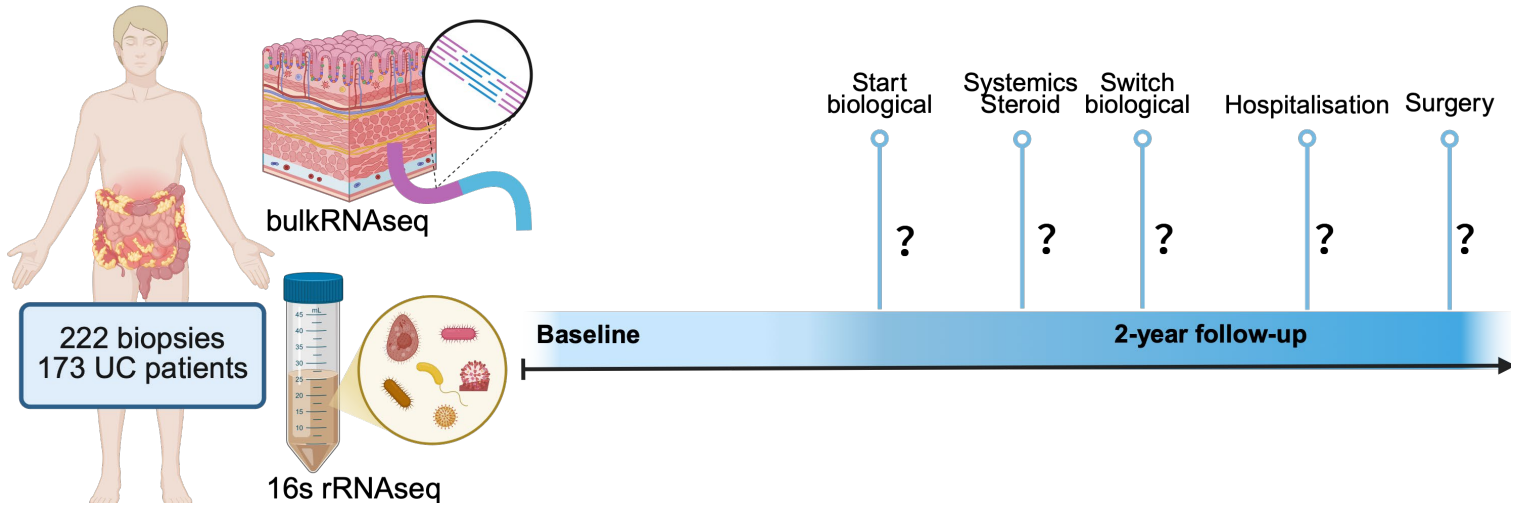
Tran *et al*, DDW 2024; manuscript submitted

Individual treatment response dynamics measured by patient reported outcomes and biomarkers

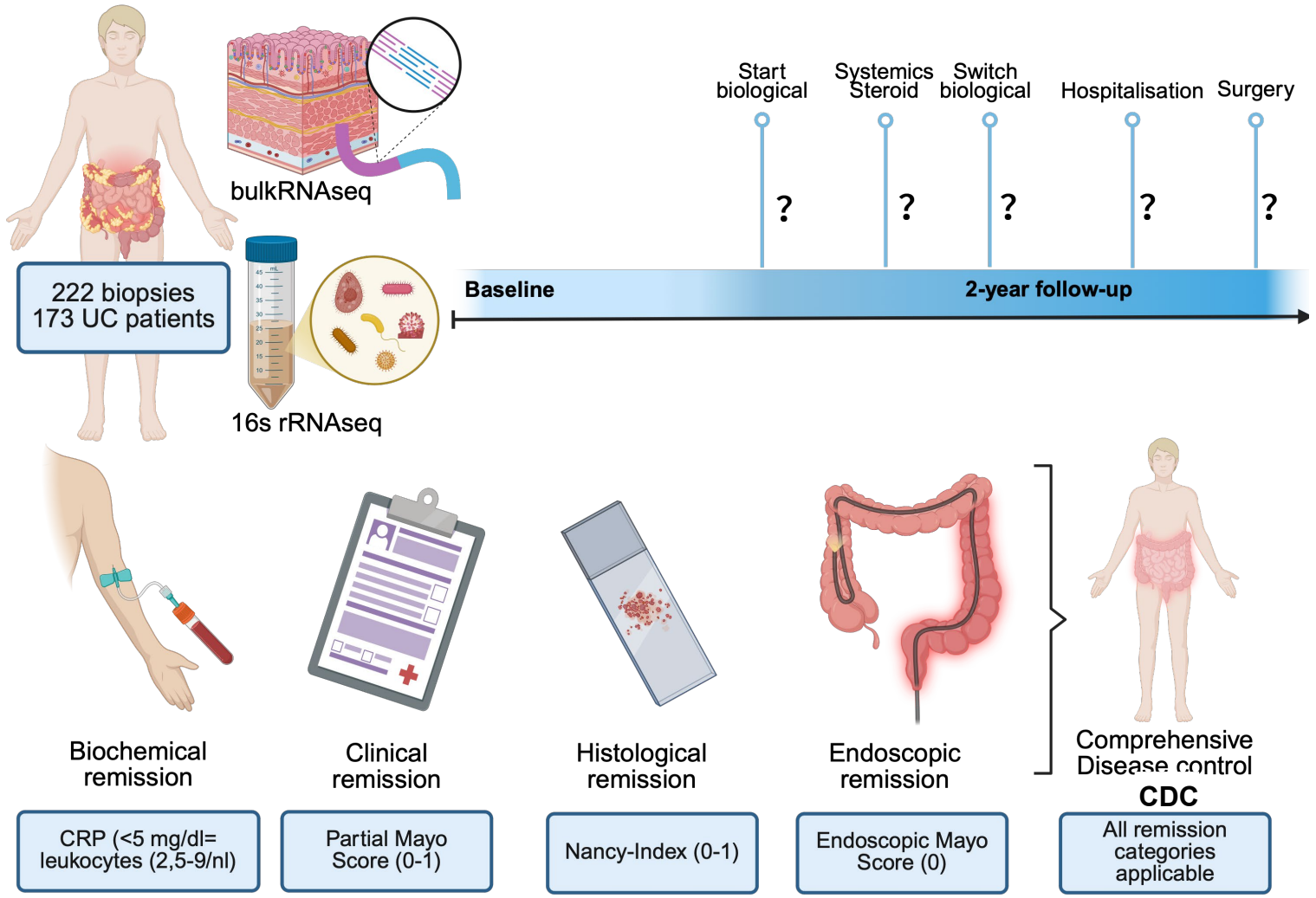


Schreiber, Aden, Tran, Rosenstiel, Gut 2025

Retrospective study design: different UC patients at different disease stages



Retrospective study design: different UC patients at different disease stages



A molecular definition of comprehensive disease control

ImmUniverse

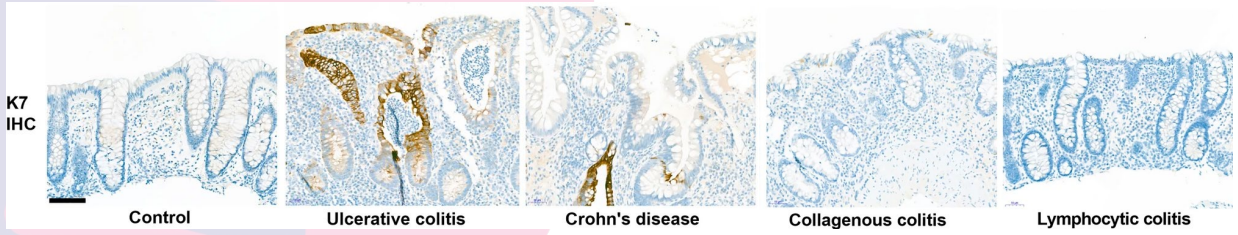
KRT7 encodes keratin 7.

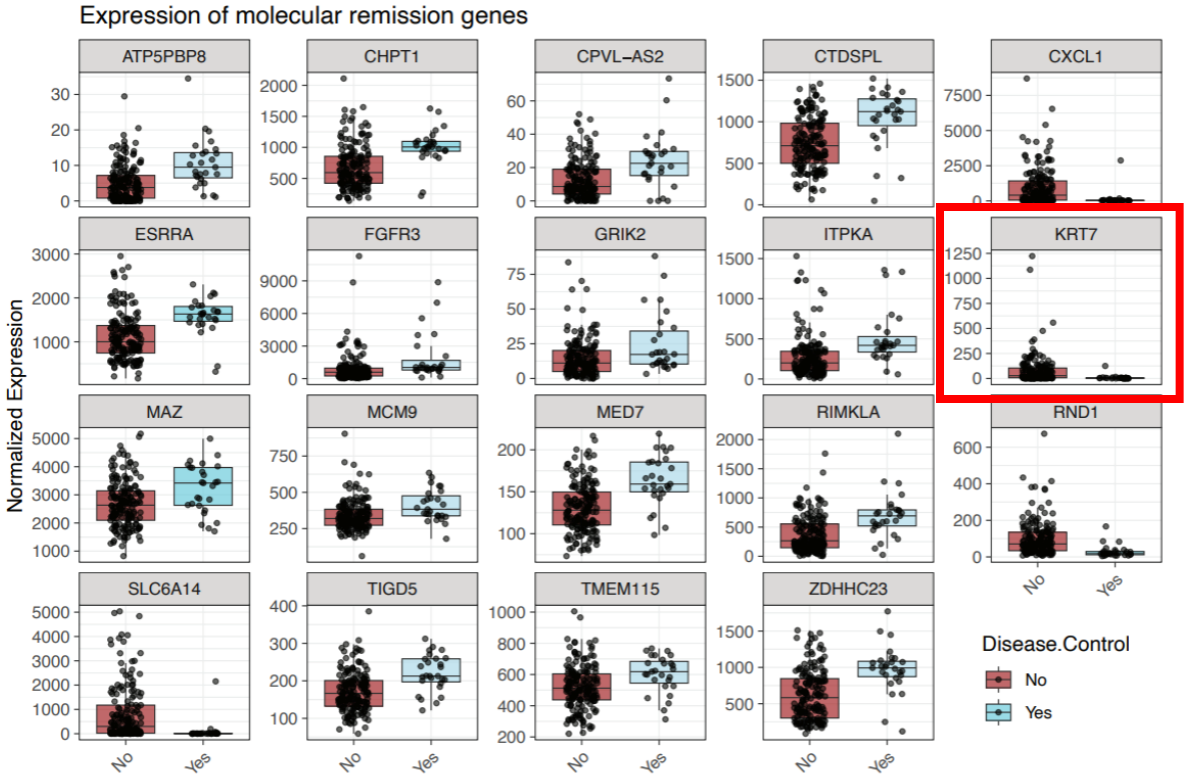
It is not found in healthy colonocytes.

Finnish researchers show that ***KRT7* is expressed *de novo*** in colonocytes of patients with IBD and correlates with disease severity.

At the same time, it is **not expressed de novo in other inflammation** of the colon, making it specific to IBD.

Polari et al. Scientific Reports 2022
Tenhamie et al. Scientific Reports 2023





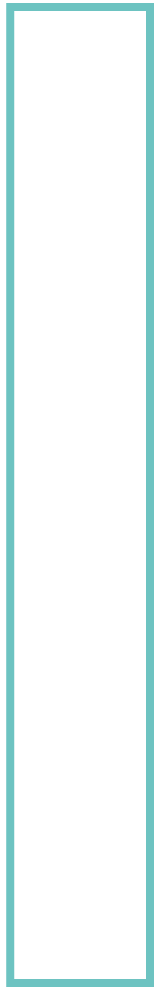
A molecular definition of comprehensive disease control

General downregulation of inflammatory response, apoptosis, epithelial-mesenchymal transitions, IFNG response, and TNF signaling.

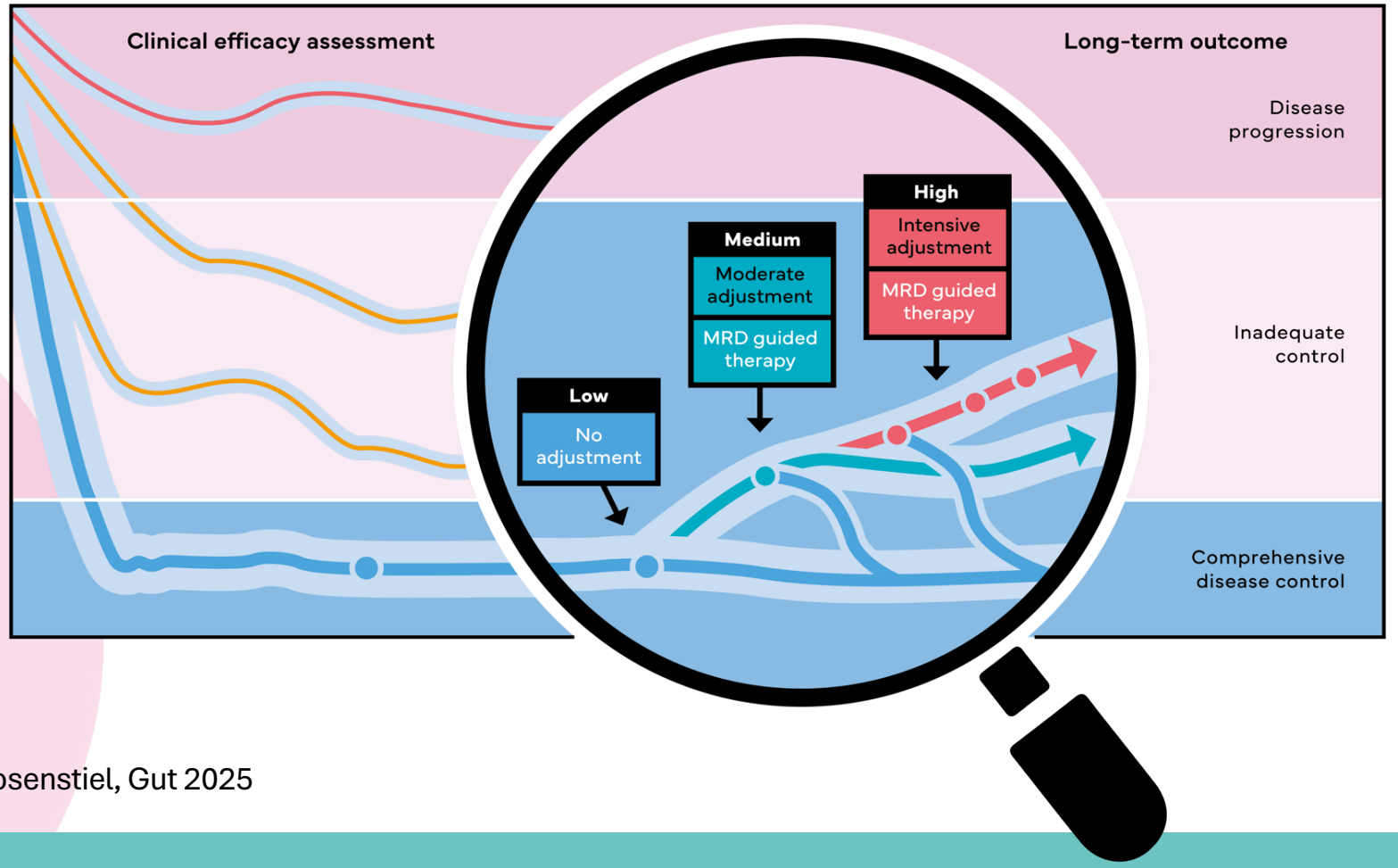
General upregulation of adipogenesis, fatty acid metabolism and oxyPhos

Group of patients with Molecular CDC?

(LachClos: Lachnoclostridium)
(LachSpi: Lachnospiraceae)



MRD = Minimal Residual disease -
A way to monitor patients without detectable signs and symptoms of IBD?



Schreiber, Aden, Tran, Rosenstiel, Gut 2025

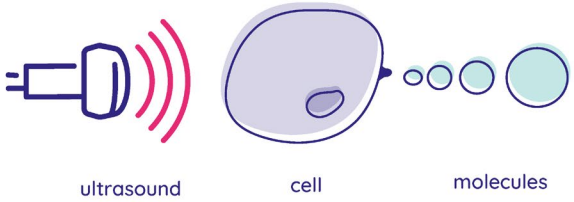
ImmUniverse

Dynamic changes in extracellular vesicle-associated miRNAs elicited by ultrasound in inflammatory bowel disease patients

Diagnosis of IBD is challenging and most often requires invasive methods

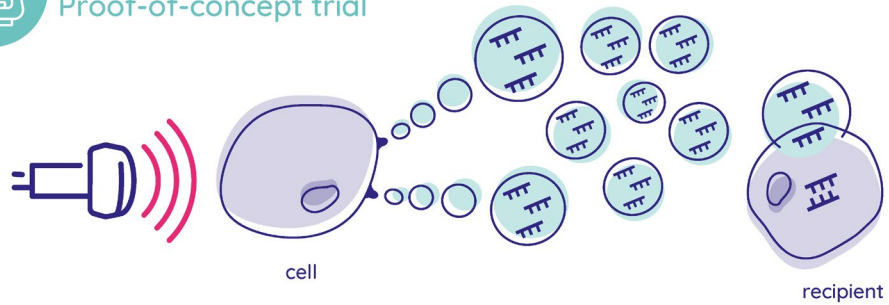
Ultrasound assessment may be a suitable alternative

Idea



Studies in in vitro experiments demonstrated ultrasound waves can trigger cells to release different molecules

Proof-of-concept trial



- Focus: extracellular vesicles (small bubbles produced by cells)
- Vesicles can be taken up by other cells
- Contain molecules like micro-RNAs (regulate gene programs)

- Ultrasound induces changes in blood molecular marker in IBD patients (vesicle number and miRNAs in vesicles are altered)
- Effect strongest in IBD patients with high disease activity

Outlook

Potential for further testing and studies

Exploring "sono-induced" biomarkers

Possible clinical value (e.g., predicting long-term disease course)

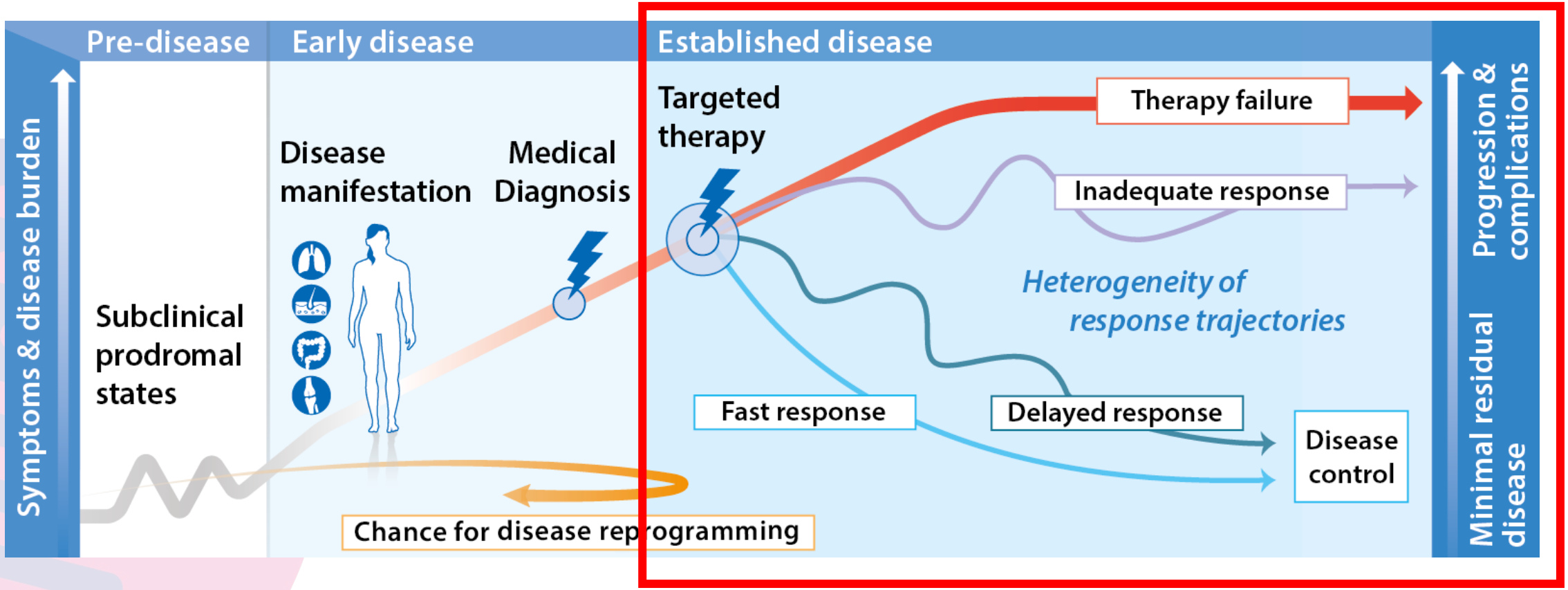
Cooperation between CAU and HUNIMED

ImmUniverse

Heterogeneity of inflammatory bowel disease

Heterogeneous **natural histology, site of manifestation, disease trajectory**

Concept figure from:
ExC PMI Renewal Proposal



Biologics Biomarker Cohort Study

ImmUniverse

PMI Precision Medicine in Chronic Inflammation

Moderate to severe CD or UC

one MoA

- anti-TNF
- anti-integrin
- anti-IL-12/23p40
- anti-IL-23p19
- JAKi
- S1PR

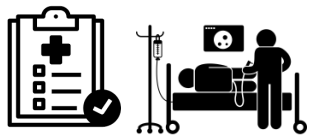
consider restart with next MoA

NO

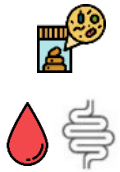
Response? Remission?

Response? Remission?

Week 0	Week 6	Week 14	Week 26	Week 52	Week 78	Week 104



Anamnesis
Disease activity scores
PROs



Biomaterials

Multicenter recruitment

ImmUniverse

UNIVERSITY OF CAMBRIDGE

A. Kaser
Cambridge, UK

Amsterdam UMC
Universitair Medische Centra

G. d'Haens
Amsterdam,
The Netherlands

UZ LEUVEN

S. Vermeire
Leuven, Belgium

CHRU NANCY

L. Peyrin-Biroulet
Nancy, France

C A U
Kiel University
Christian-Albrechts-Universität zu Kiel

Coordinator
S. Schreiber
Kiel, Germany

S. Howaldt
Hamburg, Germany

J. Klaus
Ulm, Germany

Total: 325 patients

Profiling the ImmUniverse prospective UC cohort

ImmUniverse

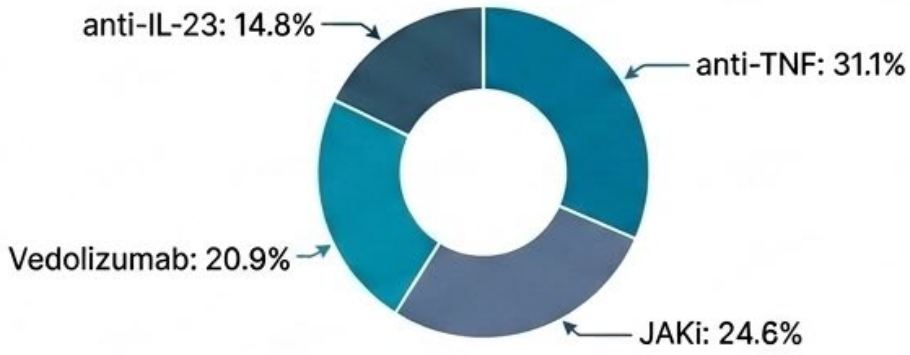
N = 325

Multicenter Recruitment: CAU, AMC, UCAM, UULM, KUL, Hamburg

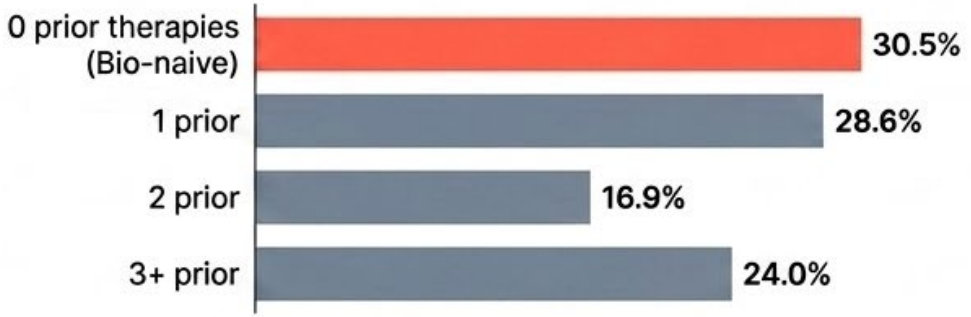
56.6% Male

Mean BMI: **25.3**

Mechanism of Action (MoA)



Treatment History (Prior Therapies)



Response outcomes at week 14

Baseline Severity

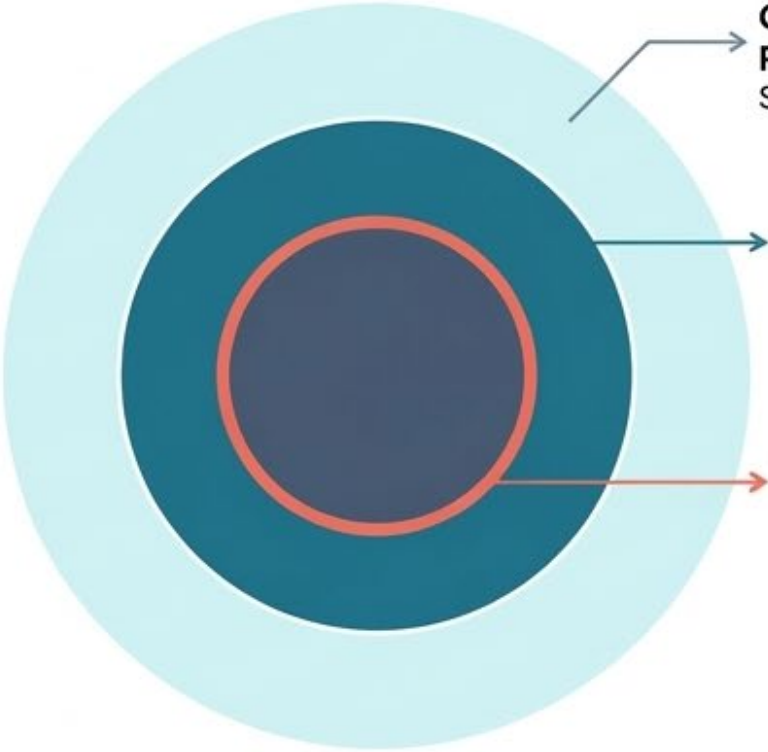
Partial Mayo Score (PMS)	Mayo Endoscopic Score (MES)	Nancy Index (Histology)
Mean: **5.68**	Mean: **2.42**	Mean: **2.86**

Systemic Inflammation

Mean CRP:
10.54 mg/L

Mean Leucocytes:
9.23 /nL

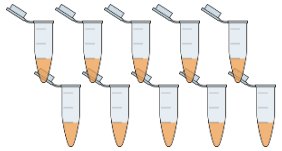
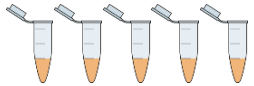
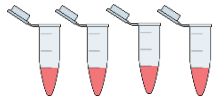
Week 14 Remission Funnel



Biomaterial collection

ImmUniverse

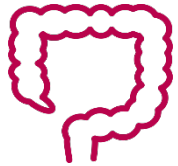
Blood (50 mL)

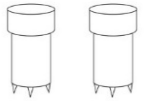
Serum		10 aliquots
Plasma		5 aliquots
PBMC		3 aliquots
PAX		2 tubes
Smarttube/ PROT1		6 aliquots
EDTA		1 x 2.7mL tube

Stool

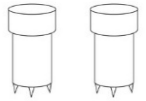
3 aliquots native
3 aliquots Stratec

Biopsies (only baseline, week 14/52/104)





Freezing medium
(inflamed / non-inflamed)

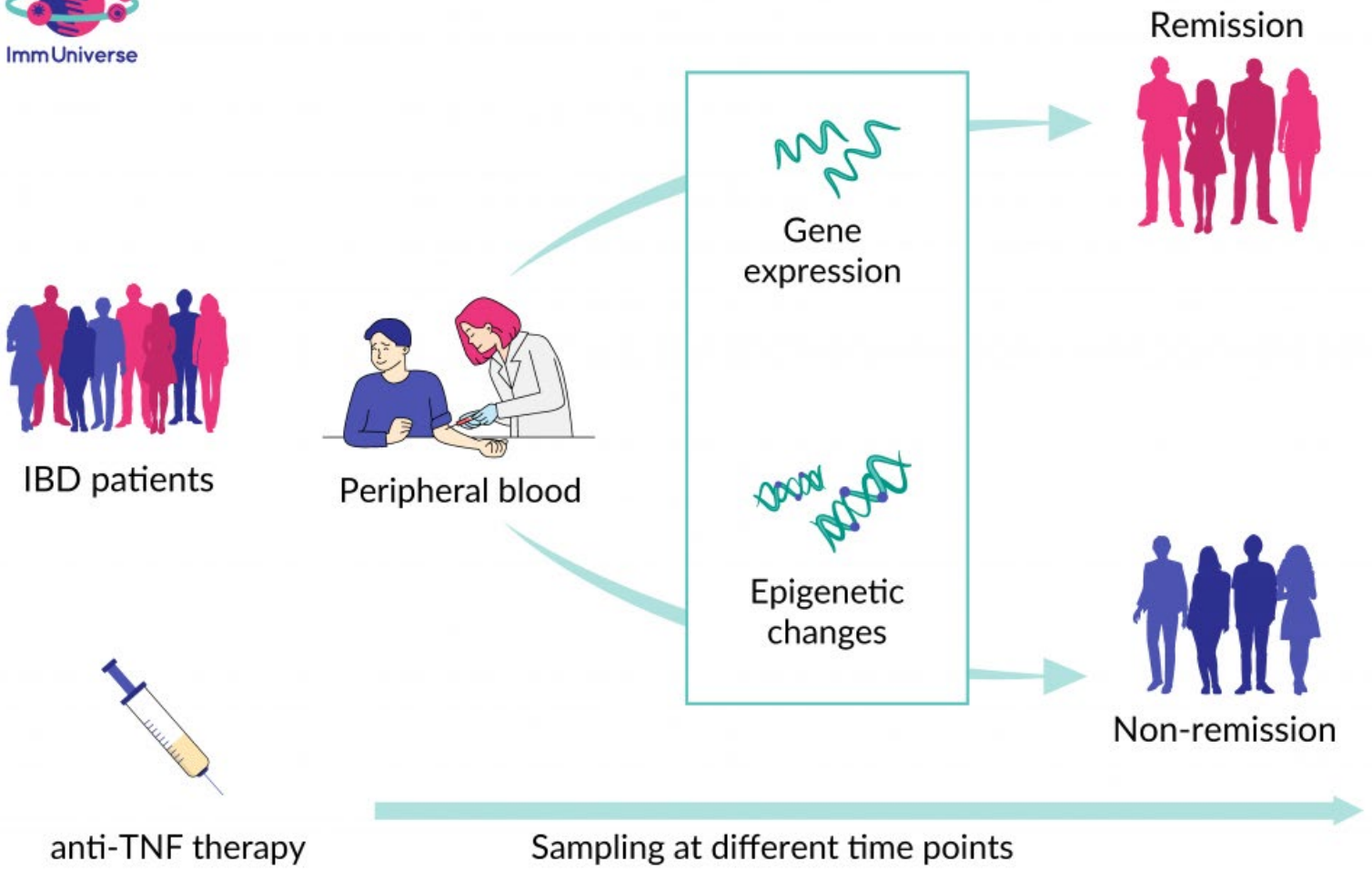


Native (w/o medium)
(inflamed / non-inflamed)

Analysis plan

ImmUniverse

Sample type	Sample type	Omics Layer	Technology/ Platform
blood	Serum	EV-miRNA	EV smallRNA-seq
	Plasma	**Proteomics**	OLINK HT
	EDTA	**Methylation**	**EPIC array**
	Serum	Metabolome	LC-MS via Orbitrap
	Smarttube	Immunophenotypes	43-color flow
	PAXGene	**RNAseq**	**Illumina**
	PBMC	**CITE-seq / scRNA-seq**	**10x FLEX + Total-Seq C**
Stool		Gut microbiome	Shotgun metagenomes
Biopsies in freeze medium		**CITE-seq / scRNA-seq**	**10x FLEX + Total-Seq C**
Biopsy frozen w/o medium		Imaging mass cytometry	Hyperion
		Spatial Lipidomics	In-house pipeline
		RNAseq	**Illumina**
Biopsies as FFPE block		**Spatial Transcriptomics**	**10x Visium HD**
		Multiplex IF (100 proteins)	**MACSima**



Blood markers:

Dynamic changes within 2 weeks were predictive for therapy success after 3 months

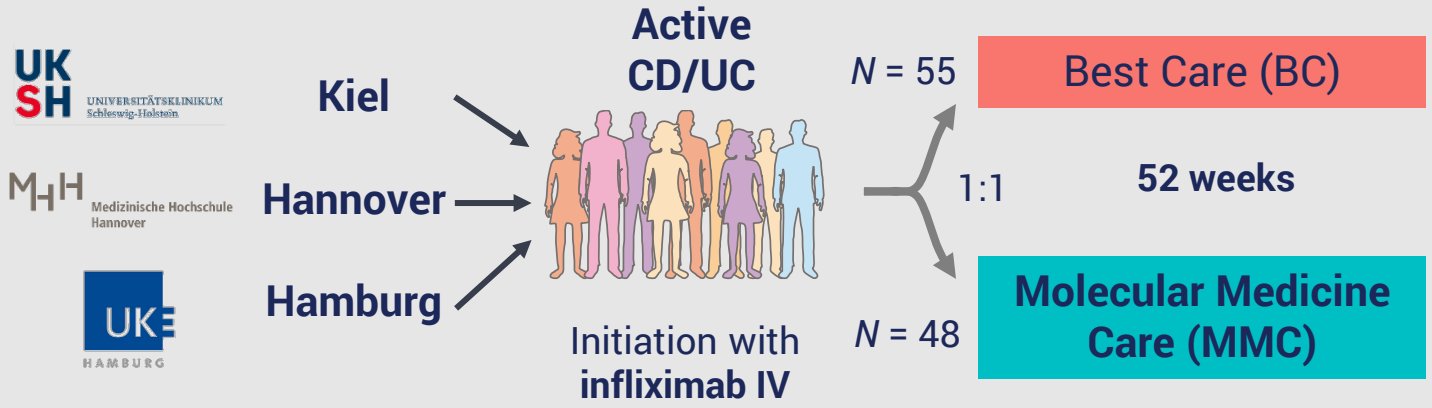
→ Basis for a prospective study

Mishra, *et al*, 2022 Genome Med

Study aim and trial concept

GUIDE-IBD: Prospective, multicentre, randomised controlled trial (DRKS00032030)
Funded by the **German Federal Ministry of Education and Research**

Bundesministerium für Bildung und Forschung



Both arms:
- Structured longitudinal board presentations & decisions

Additionally in MMC:
- Blood and biopsy RNA panels*
- Pharmacokinetics modelling**
- Structured molecular reports

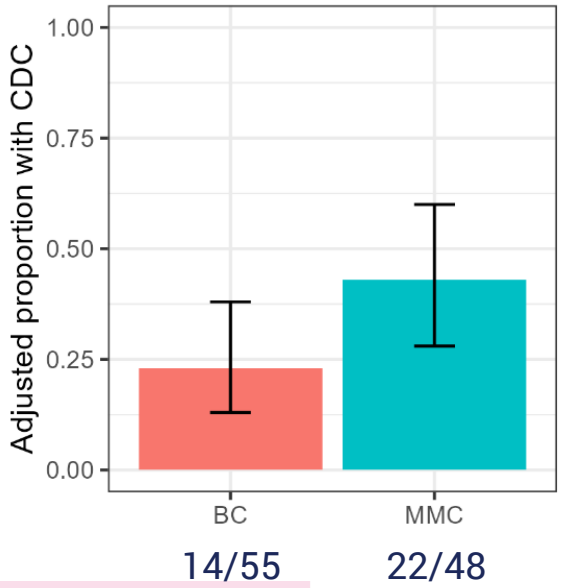
* Based on: Mishra, …, Tran *et al*, 2022 Genome Medicine
** Based on: Schräpel, …, Tran *et al*, 2021 Pharmaceutics

Primary research question:
- Does biomarker-informed therapy guidance improve **disease control at one year**?

Primary outcomes in the mITT population

Primary endpoint

Disease Control at week 52



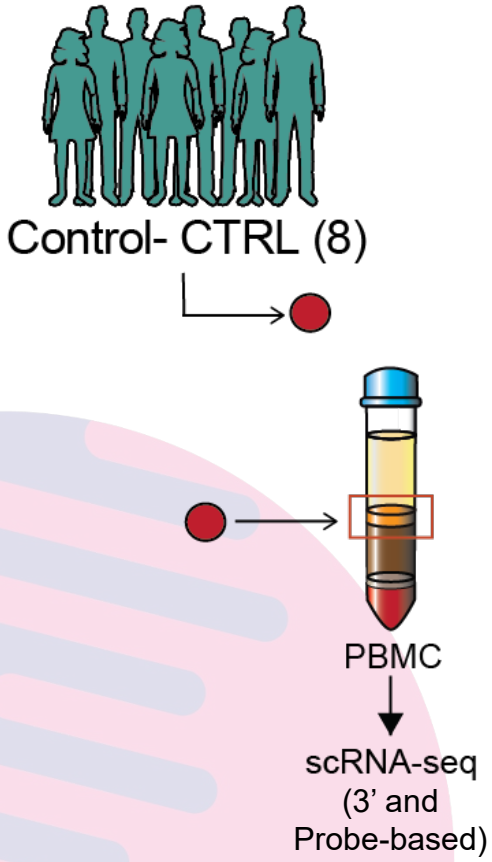
Primary endpoint was **Disease Control (DC) to week 52**, defined as combination of

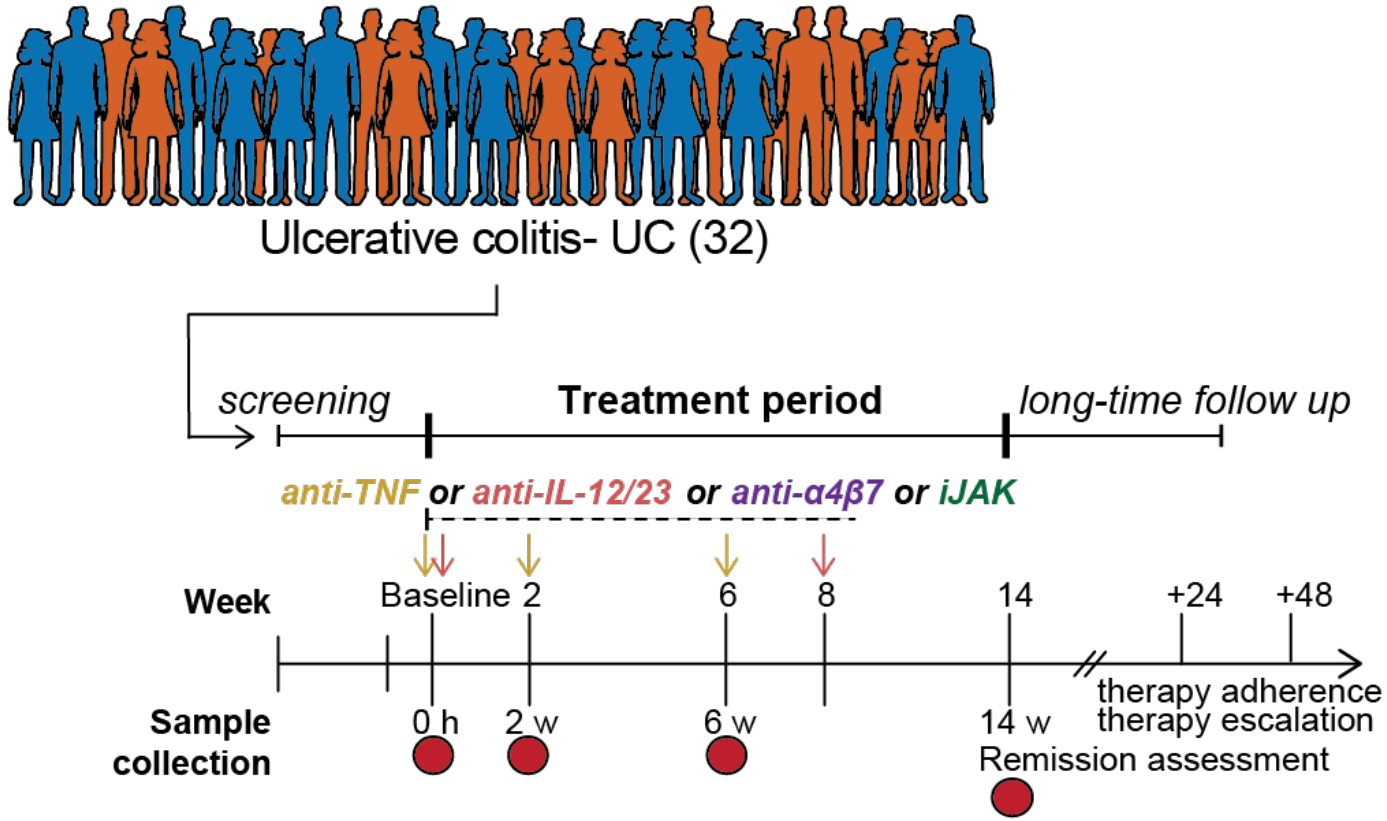
- clinical remission (CDAI <150; PMS ≤ 1)
- endoscopic remission (SES-CD ≤4; MES ≤1)
- biomarker normalization (CRP <5 mg/L, fCal <250 mg/g)

Modified from:
Schreiber et al, UEG Journal 2024; Schreiber et al, JCC 2024

Adjusted OR = 2.53 (95% CI: 1.09-5.86, *P* = 0.031)

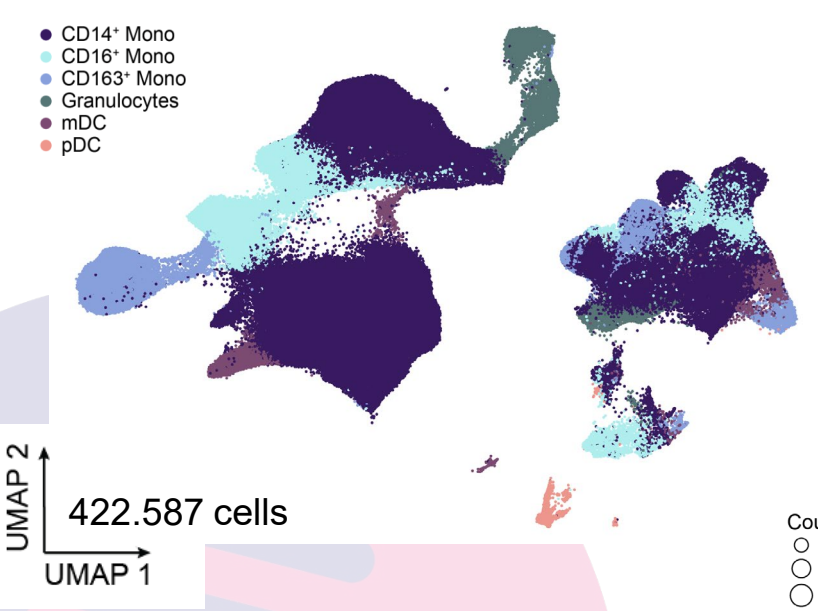
Blood single cell analysis

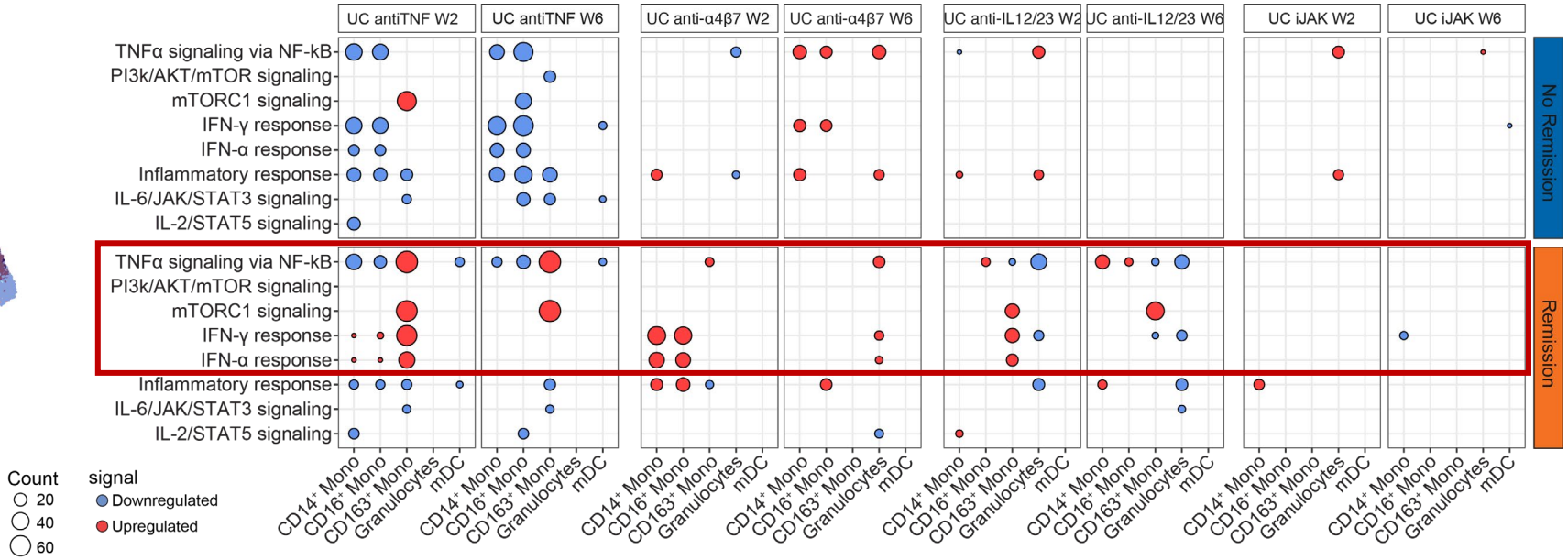




Expression profile of 175 samples.

Antibody-based drugs mounted a strong IFN signature at early timepoints.



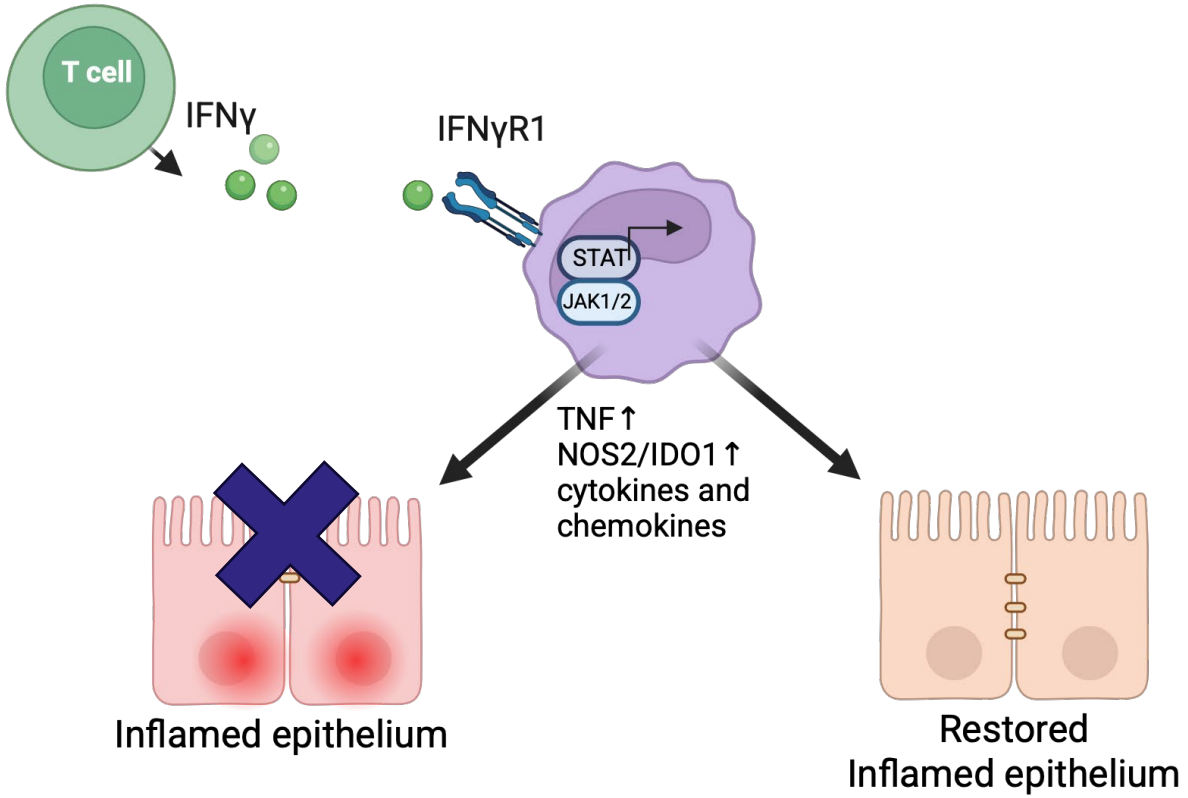


iJAK: IFN-γ downregulation.

> Signal Dampening: cytokine blockade

Therapy-specific temporal rewiring of IFN-γ programs in myeloid lineage

- Myeloid recalibration
- Immune redistribution



Early biomarkers of Response

Summary

- We defined Comprehensive Disease Control as a new, desirable outcome for UC patients.
- We identified molecular markers that are surrogates for CDC and thus predict long-term outcomes.
- Ultrasound and LIPUS have potential additional value to access inflammation or minimal residual disease.
- We identified blood-based biomarkers that predict therapy success to anti-TNF – and proved their clinical utility in a study called GUIDE-IBD.
- Further biomarker discovery through new multi-omics and high-resolution analysis methods is ongoing.

Thank you!

ImmUniverse

Amsterdam UMC
Universitair Medische Centra

HaFCED
Hamburgisches Forschungsinstitut für chronisch entzündliche Darmerkrankungen

Universitäts Klinikum ulm

CAU
Kiel University
Christian-Albrechts-Universität zu Kiel

Radboudumc
university medical center

CHRU NANCY

UZ LEUVEN

Lilly

ITTM
Information Technology for Translational Medicine

University of Cambridge

HU Humanitas University

Pfizer

uni.lu
Université du Luxembourg

sanofi

Q&A

Yasemin Zeisl, EPF

Closing

Resources

ImmUniverse

Check out project materials and information at:

www.immuniverse.eu

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Thank you!