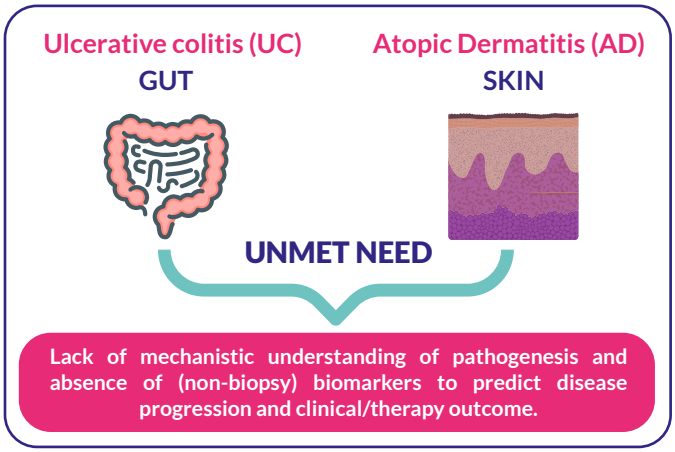
ImmUniverse

Transforming Diagnosis and Treatment for Ulcerative Colitis and Atopic Dermatitis

Background

Immune-mediated inflammatory diseases (IMIDs) are debilitating conditions characterized by dysregulated immune responses leading to destructive chronic inflammation. Ulcerative colitis (UC) and atopic dermatitis (AD) are examples of IMIDs, for which unmet clinical treatment needs exist.

An optimal therapeutic approach for these diseases aims to gain rapid control of inflammation and to prevent tissue damage in order to improve patient's quality of life and, if possible, achieve long-term disease remission. Although biologic therapies have provided clinical benefits to patients, these goals are still poorly met, due to the limited knowledge of the underlying mechanisms of immunopathology and the lack of predictive biomarkers that would allow proper patient stratification.



Vision

ImmUniverse aims to play a transformative role for diagnosis and therapy of IMIDs by paving the way for a truly personalized disease understanding. The complex and ambitious nature of this project requires the unique collaborative nature of the ImmUniverse consortium, bringing together deep expertise and experience in disease understanding, technology, clinical trials and patient management from academia, SME and industry partners. This cross-industry expertise will be the key to the success of ImmUniverse and advance disease knowledge to the benefit of patients.

> "ImmUniverse is a highly integrated and transdisciplinary consortium that proposes a Multi-Omics approach using a broad range of molecular profiling techniques to identify signatures of local and circulating biomarkers and mechanistic principles that are informative of disease severity and future disease progression."
>
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Key steps

(1) A large cohort of retrospective samples from industry-sponsored clinical trials and academic studies, with two main sample types (tissue, serum) collected retrospectively and longitudinally from patient cohorts suffering from ulcerative colitis and AD will be analysed using omic techniques in comparison in comparison to healthy controls to identify a first set of integrated tissue and liquid signatures representative of the full spectrum of disease activity states.

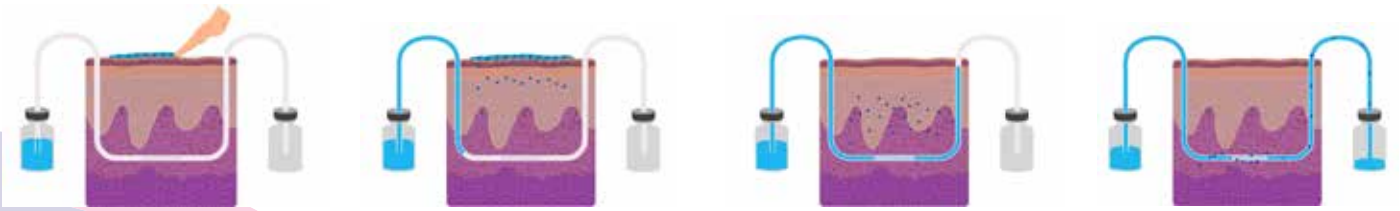
(2) In parallel, a prospective longitudinal observational clinical study will be conducted to prospectively collect multiple sample types (blood, serum, peripheral blood mononuclear cells, exosomes), stool and tissues (bulk, dissociated cells) from the same individuals at multiple time points.

(3) A further challenge of ImmUniverse will be to evaluate whether the non-invasive technologies, dermal open-flow microperfusion in the skin and low-intensity pulsed ultrasound stimulation in the gut, can be used as disruptive liquid biopsy technologies, in a translational setting to establish specific disease signatures in blood and explore novel technologies to overcome currently invasive approaches and improving patient compliance, respectively.

Our Methods: Dermal open-flow microperfusion (dOFM)

dOFM is a minimally invasive in-vivo technique using macroscopic probes placed in the dermis to sample interstitial fluid. Probes are inserted about 0.8 mm deep, running parallel to the skin. A precise fluidic pump maintains a constant flow of perfusate within the probe at 1 µl/min. A specific exchange area in the dermis allows for interchange between perfusate and interstitial fluid, capturing various tissue components, including lipophilic substances, large molecules like antibodies, and mobile cells. dOFM enables monitoring time-dependent processes hourly, with each sampling session lasting up to 72 hours.

This can be repeated as needed, facilitating baseline and pharmacodynamic response assessment following a stimulus, such as treatment. Both dOFM and blood sampling will be conducted over 8 hours, adhering to the defined sequence.



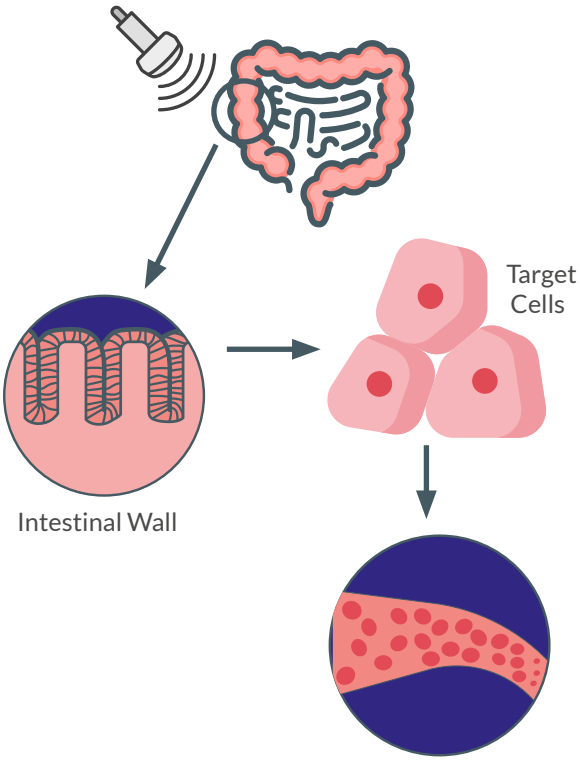
Our methods: Low-intensity pulsed ultrasound (LIPUS)

LIPUS has been employed to release cell vesicles and molecules, hinting at the potential for non-invasive localized stimulation of patients‘ damaged tissue microenvironment. This may trigger specific factor release from cells, which could then be carried by the lymphatic system into the peripheral blood, revealing a circulating signature of tissue status.

ImmUniverse aims to optimize this process, evaluating frequency, intensity, exposure time, and duty cycle through systematic in vitro tests. An appropriate setup will prevent wave reflection/absorption.

Clinical studies:

1. in vitro study on ulcerative colitis (UC) patients‘ cells,
2. mice study to determine effective LIPUS parameters and effects without worsening animal disease,
3. pilot study on UC patients to validate LIPUS as a liquid biopsy reflecting tissue status, once parameters are established, and
4. clinical study on UC patients to assess disease progression monitoring using this approach.



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