INNODIA
Networking Event
2024

April 11th & 12th, 2024

Leuven (Belgium)

Social and educational gatherings
that want to unite all INNODIA stakeholders,
fostering a fertile ecosystem
for developing new cures and promoting disease-modifying therapies
for people living with type 1 diabetes

EVENT information

WHAT FOR

Enable all INNODIA stakeholders to efficiently connect, dialogue, and build a thriving ecosystem through education and networking opportunities.

WHO can attend

All INNODIA stakeholders are welcome, including INNODIA members, people with T1D (INPACT, Patient Associations), experts, as well as medicine developers, investors, funders, and partners - both those already involved and those interested in joining the Network.

WHERE

The opening dinner will take place in the beautiful brewery De Hoorn in Leuven – the birthplace of Stella Artois (Sluisstraat 79 – Leuven). We will spend the whole Friday at the Faculty Club - the breath taking setting of the restored buildings of the Grand Beguinage (Groot Begijnhof 14, Leuven).

HOW to register

To secure your participation, please register here (or visit our web site www.innodia.org under "News and Event").
Seats are limited and registration will close once we reach our maximum capacity.

Event EXPENSES

INNODIA is pleased to cover meeting-related expenses; however, participants are kindly requested to cover their own travel and hosting-related costs.

AGENDA - April 11th, 2024

18:00 – 22:00

17:30 **Registration open**

Participants are welcome to arrive at the Brewery before the opening lecture to register, enjoy a drink and visit the site.

19:00 - 20:00 INNODIA **opening lecture**

INNODIA**.org: one year down, countless possibilities ahead for all our stakeholders**

Chantal Mathieu and Manuela Battaglia

After a warm welcome by the INNODIA Board Chair, Chantal Mathieu, the Managing Director of INNODIA, Manuela Battaglia, will provide a comprehensive overview of the milestones achieved in the first year of INNODIA and share a vision for the exciting opportunities that lie ahead in the upcoming year.

20:00 - 21:00 Dinner

21:00 - 22:00 INNODIA Chit Chat

Embrace the opportunity to connect with every constituent of the INNODIA ecosystem and make the most of the chance to thoroughly explore the network.

De Hoorn

Sluisstraat 79 – Leuven

Heart and soul of the brewery

Discover and experience the history of the brewery in the impressive Brewing Room. Mix history and present and make your own sparkling brew.

The Brewing Room is a protected heritage site and has been fully restored to its original state! It doesn't get more unique.

AGENDA - April 12th, 2024

8:00 – 14:00

8:45 – 9:30 INNODIA **General Assembly (GA) Meeting**

All INNODIA Members are invited to participate, and Full Members are requested to exercise their voting rights. ***Breakfast will be provided*** *(from 8:00 AM)*

GA agenda will be shared with all INNODIA Members before the meeting.

9:45-10:00 **Welcome to the** INNODIA **Network Event: Unveiling Participants, Exploring Purpose, and Charting Our Common Path**

Manuela Battaglia

10:00-13:00 **Empowering each internal** INNODIA **stakeholder: the key to successfully accelerating the development of T1D modifying therapies.**

This morning's session is dedicated to the ***internal INNODIA stakeholders,*** *offering a deep dive into the pivotal role of each participant within the INNODIA framework. Join the session to acquire a comprehensive understanding of the INNODIA ecosystem and shape your contribution to propel progress forward.*

10:00 People living with Type 1 Diabetes

• INPACT: The INNODIA People living with T1D Community

ANA ALVAREZ PAGOLA

Gain a crystal-clear understanding of INPACT: what it is, the rationale behind its creation, how it was built, and the exciting opportunities it holds for People with Diabetes

• The INNODIA Paradigm: A genuine 'patient-centric' framework across every stage of medicine development

LAURA DAL ZOTTO

Transitioning from a patient-centric slogan to tangible patient contributions at every stage of medicine development: unveiling the INPACT roadmap

• The echo of an INPACT Associate: a real INNODIA experience

SOFIE MOORS

Listen to the experience of a young patient enrolled in an INNODIA clinical trial and her amazing contribution to designing a future study for a biotech.

→ Unlocking the benefits of becoming an INPACT associate or ambassador & Question time

FRANCESCA ULIVI & JAIVIR PALL

10:40 Scientists | Physicians

• INNODIA Members

MANUELA BATTAGLIA

Get to know all the INNODIA members: who they are, what they do, and how they contribute to the health of the ecosystem

• The INNODIA Paradigm How Investigators in academic environments can transform their expertise into valuable contributions for medicine developers

ROBERTO MALLONE

Grasp the reasons why academic knowledge and expertise should not be confined within academic walls if we aspire to achieve improved and expedited curative therapies for individuals living with Type 1 Diabetes

• The echo of an INNODIA Member: a real INNODIA Scientist experience

TIM TREE

Explore the insights shared by an internationally recognized expert in immune biomarkers, contributing to the mechanistic studies of clinical trials, and discover his original contributions to the design of new studies for medicine developers

→ Unlocking the benefits of becoming an INNODIA Member & Question time

ELENA BRUNO & MANUELA BATTAGLIA

11:20 – 11:40 INNODIA Mingle Mocha Moment

11:40 Clinical Trial Site Teams

• The INNODIA Clinical Trial Site (CTS) Network

ABRIANNA DALMAN & NICOLE KOLLER

Attain a comprehensive understanding of the significance of being an INNODIA-accredited clinical trial site. These sites have the capability to enrol subjects at all stages of T1D, are fully equipped, and possess a strong commitment to conducting intervention clinical trials. They can benefit from collaboration with INNODIA referral partners, leading to increased recruitment rates and pace and are supported by a dedicated INNODIA team and program throughout the execution of clinical trials.

• The INNODIA Paradigm: why accredited CTS can be real game changers in the development of disease modifying therapies

THOMAS DANNE

The limited number of efficient clinical trial sites capable of contributing to intervention trials in a timely manner is a crucial challenge for medicine developers during their clinical developmental stages. Discover how INNODIA is diligently addressing this issue by crafting a finely tuned accredited and supportive system.

• The echo of a CTS Member: a real experience from the INNODIA Network

CLAUDIA PIONA & ALESSANDRO CSERMELY

Hear the experience of two clinical trial site teams that aspired to enter the arena. Learn how INNODIA played a pivotal role in enabling these sites to successfully embark on this journey.

→ Unlocking the benefits of becoming an accredited CTS or referral partner & Question time

ABRIANNA DALMAN & NICOLE KOLLER

12:20 Team of Expert Advisors

• The INNODIA model: from the "I know everything" Expert to the Team of Expert Advisors

CHANTAL MATHIEU

Our Members include a number of top-level key opinion leaders internationally recognized for their expertise and ability to advise on all major topics in the field of biomedical research in T1D. Discover how INNODIA assembles dedicated teams of expert advisors, collaboratively driving the advisory process in alignment with the specific requests of medicine developers.

• The INNODIA Paradigm: Why Proficiently Reviewing a Scientific Project Falls Short in Assisting Medicine Developers

JAY SKYLER

Discovering the distinction: offering constructive advice to medicine developers vs. providing expert scientific opinions. Uncover what medicine developers truly need and expect from one of the most sought-after advisors in the field of T1D modifying therapies.

• The echo of an INNODIA Expert: a real INNODIA Junior Advisor experience

DARJA SMIGOC SCHEWIGER

Gain Insight into the challenges and rewards of joining an INNODIA team of expert advisors, focused on medicine developers' requests, directly from a junior expert.

→ Unlocking the benefits of becoming an INNODIA Expert & Question time

CHANTAL MATHIEU & MANUELA BATTAGLIA

13:00 – 14:00 INNODIA Lunch-time Liaison

Lunch Speed Meetings

Seize the unprecedented opportunity for one-on-one 10-minute (speed!) meetings with funders, investors, and INNODIA partners, crafting the opportunities you seek. Address your inquiries about INNODIA directly with the INNODIA Managing Team.

AN ONLINE BOOKING SYSTEM WILL BE SHARED BEFORE THE MEETING

AGENDA - April 12th, 2024

14:15 – 17:00

14:15 -17:00

Navigating the landscape of T1D medicine developers: upcoming innovations and unveiling their needs

*Join us this afternoon for an exclusive session tailored for the **external INNODIA stakeholders**. Discover the cutting-edge pipelines of **medicine developers** investing in T1D and explore how they aim to leverage academic expertise and competence. Stay informed about the exciting activities we are collaboratively developing with our **partners**.*

A FINAL LIST OF ALL SPEAKERS WILL BE PROVIDED BEFORE THE MEETING

All in all, embrace exciting opportunities to deepen your engagement in the INNODIA network and become an active contributor in facilitating the development of disease-modifying therapies for individuals living with type 1 diabetes, everywhere

The Faculty Club
Groot Begijnhof 14, Leuven

An inspiring oasis of calm in Leuven city center

Faculty Club in Leuven is a unique event location. The breath-taking setting of the restored buildings of the Grand Beguinage make it the ideal place for our event. There is a good reason why the site was made UNESCO World Heritage in 2000.

SPEAKERS SPARKS

Cast in order of appearance

• Chantal Mathieu
President of the INNODIA Board - Head of Diabetes Lab at KU Leuven and Head of Endocrinology Dep. at UZ **Leuven (BE)**

• Manuela Battaglia
INNODIA Managing Director – **Milano (IT)**

• Ana Alvarez Pagola
INNODIA INPACT Coordinator – **Madrid (SP)**

• Laura Dal Zotto
INNODIA INPACT Coordinator – **Milano (IT)**

• Sofie Moors
INNODIA Clinical Trial Participant – **Antwerp (BE)**

• Francesca Ulivi
INNODIA Board Member; INPACT Advisor – **Milano (IT)**

• Jaivir Pall
INPACT Advisor – **London (UK)**

• Roberto Mallone
INNODIA Board Member – Prof. of Immunology, Diabetologist and Research Team Leader; INSERM Cochin Institute – **Paris (FR)**

• Tim Tree
INNODIA Board Member – Prof. of Immune Regulation and Immuno-therapy; King's College – **London (UK)**

• Elena Bruno
INNODIA Network & Partnerships Manager – **Milano (IT)**

• Abrianna Dalman
INNODIA CTS Network Manager – **Antwerp (BE)**

• Thomas Danne
Vice-President of the INNODIA Board - Hannoversche Kinderheilanstalt – **Hannover (GE)**

• Claudia Piona
Research Fellow at the Pediatric Diabetes & Metabolic Disorders University of **Verona (IT)**

• Alessandro Csermely
Research fellow at the Department of Endocrinology, Diabetology and Metabolic Disease University of **Verona (IT)**

• Nicole Koller
INNODIA CTS Network Coordinator – **Hannover (GE)**

• Jay Skyler
Prof. of Medicine, Pediatrics, & Psychology; Univ. of Miami Leonard M. Miller School of Medicine – **Miami (USA)**

• Darja Smigoc Schewiger
INNODIA Expert – Attending Pediatrician and Consultant; University Medical Centre Ljubljana – **Ljubljana (SL)**

MEDICINE DEVELOPERS

• Diamyd Medical

A public Swedish biotech company in late clinical phase developing precision medicine therapies for autoimmune diabetes (T1D and LADA). The lead asset, Diamyd® (rhGAD65 formulated in aluminium hydroxide), is an antigen-specific immunotherapy for the preservation of endogenous insulin production. Patients carrying the HLA DR3-DQ2 have been identified as the responders to Diamyd treatment in a large-scale meta-analysis whose results were confirmed in the Phase 2b trial DIAGNODE-2. Diamyd Medical is currently building up a wholly-owned GMP biologics manufacturing facility for the manufacturing of rhGAD65, with the potential for a broader CDMO and analytics service.
Presented by: ***Chris Nowak*** *(Chief Medical and Business Officer)*

• IMCYSE

A clinical-stage biopharmaceutical company committed to advancing the development of a new class of specific immunotherapies called Imotopes. Imotopes™ are simple peptide molecules, injected subcutaneously, which stimulate an immune response that specifically blocks the autoimmune pathways without harming the rest of the immune system. They have the potential to have long lasting effects that stop the progression of the disease. The Imcyse approach is unique and distinct to general tolerance induction or overall "immune-suppression". The most advanced program is for T1D where the company has designed and successfully completed, with the support of INNODIA EU-Projects, a 100+ adult-patient phase 2 trial that will be reported in Q2 2024.
Presented by: ***Jean Van Rampelbergh*** *(Chief Clinical Development Officer)*

• IMMUNOCORE

A commercial-stage biotech company that has discovered, developed, and commercialized the world's first approved TCR (T cell receptor) therapy. The Company is pioneering and delivering transformative immunomodulating medicines, using its proprietary ImmTAX platform, to radically improve outcomes for patients living with cancer, infectious diseases, and autoimmune diseases.
*ImmTAAI (Immune Modulating Monoclonal TCRs Against Autoimmune Disease) bispecific molecules are designed with an organ-specific TCR fused to an immune suppressive effector function. The first candidate, IMC-S118AI, is targeted specifically to pancreatic beta cells and is intended for disease-modifying treatment in type 1 diabetes. IMC-S118AI recognizes a peptide from pre-proinsulin presented by HLA-A*02:01 on beta cells coupled with a PD1 agonist effector arm.*
Presented by: ***Stephen Megit*** *(Vice President of Business Development Europe)*

• ITB-MED

A clinical stage biotechnology company headquartered in Sweden (Stockholm) with offices in the US (New York City). ITB-MED is actively developing a proprietary antagonistic CD2-directed monoclonal antibody, TCD601 (siplizumab), with a robust pre-clinical pipeline to expand the reach of this novel, immune-modulating, approach across several autoimmune, autoinflammatory and solid organ transplant indications. ITB-MED is wholly committed to advancing and exploring the potential of TCD601, with a particular focus on its applications in immune tolerance and the spectrum of T-cell mediated autoimmune diseases.
Within T1D, ITB-MED is investigating CD2 modulation in the STRIDE study (NCT06025110) as a therapeutic option to slow or halt the destruction of insulin-producing beta cells in patients with newly-diagnosed T1D. TCD601 is a monoclonal antibody that selectively inhibits the activation and proliferation of T-cells, which are known to be important mediators in the pathogenesis of T1D and other autoimmune diseases.
Presented by: ***Alan J. Slade*** *(SVP, Global Head of Development)*

• Levicure

A start-up working on a safe and scalable treatment to provide sustainable remission for Stage 3) patients with T1D. Levicure holds an extensive patent portfolio for an orally administered therapy that consists of a combination of two FDA-approved molecules and GABA or GABA receptor agonist. A clinical pilot study shows that this combination therapy promotes full remission in recent-onset patients with T1D by restoring endogenous insulin production, stabilizing HbA1c and blood glucose levels, and substantially reducing exogenous insulin demands. Levicure's goal is to create a once-daily medication that will provide both recently diagnosed and long-term T1D patients with a safe, non-invasive oral treatment that reduces complications, promotes remission, and significantly enhances quality of life.
Presented by ***Mike Teiler*** *(Chief Pharmaceutical officer)*

• Novo Nordisk

A global healthcare company, founded in 1923 and headquartered just outside Copenhagen, Denmark. The purpose of the company is to drive change to defeat serious chronic diseases, built upon its heritage in diabetes. They do so by pioneering scientific breakthroughs, expanding access to their medicines, and working to prevent and ultimately cure the diseases that they treat.
Presented by ***Johnna D. Wesley*** *(Scientific Vice President)*

• PolTREG

A clinical-stage company focused on cell-therapy of autoimmune diseases. We are developing T regulatory cell-based products including: - polyclonal Tregs, CAR-Tregs, TCR-Tregs and antigen-specific oligoclonal Tregs. Currently, clinical stage products are autologous, but we also work on allogeneic setting. All the products are manufactured in our facility in Gdańsk. Up to now, we have completed four clinical trials in type 1 diabetes and multiple sclerosis. Over 100 patients were treated with our Tregs with good efficacy and safety profiles. The longest follow up of our patients is over 10 years now. We are looking for partnering model of collaboration in order to go into marketing authorisation with our products. We are ready for pivotal trial in type 1 diabetes and phase I/II in multiple sclerosis. There is also preclinical work with auto- and allogeneic Tregs to be developed into the clinic.
Presented by ***Piotr Trzonkowski*** *(CEO)*

• SAB Biotherapeutics

A clinical-stage biopharmaceutical company focused on developing fully human, multi-targeted, high-potency immunoglobulins (IgGs), without the need for human donors or convalescent plasma, to treat and prevent immune and autoimmune disorders. The company's lead asset, SAB-142, targets T1D with a multi-target disease-modifying therapeutic approach that aims at changing the treatment paradigm by delaying onset and potentially preventing disease progression.

*Presented by **Alexandra Kropotova** (Chief Medical Officer)*

• SANOFI

*An innovative global healthcare company with one purpose: to chase the miracles of science to improve people's lives. At the Network Event there will be a focus on FABULINUS: a randomized, controlled trial with **F**rexalim**AB**, to assess endogenous ins**ULIN** secretion in ad**U**lt and adolescent with Type 1 Diabetes on top of in**S**ulin therapy. A trial that is facilitated by INNODIA in INNODIA Clinical Trial Sites.*

*Presented by **Pascale Labard** (Clinical Operations Lead) and **Andriy Cherkas,** (Clinical Research Director)*

• "T1D Plus" Investigator Initiated Trials sponsored by Univ. of Cardiff

T1DPlus is a platform trial designed to rapidly screen combinations of agents to find the best way to preserve beta cell function following clinical diagnosis of T1D in adults (stage 3). All participants will receive verapamil and will be randomised to additional therapies which currently comprise teplizumab, ATG or golimumab. The control group (verapamil alone) will be shared between comparisons increasing the efficiency of the design. T1D Plus will open across 30 or more sites in UK, mainland Europe and Australia from Q2/Q3 2024.

*Presented by **Colin Dayan** (Trial Principal Investigator, Univ. of Cardiff)*

• "Vera-T1D" and "Ver-A-Long" Investigator Initiated Trials sponsored by the Univ. of Graz

The Ver-A-T1D study is a randomised, double-blind, placebo-controlled, parallel group, multi-centre trial in adult subjects (18 – 45 years) with newly diagnosed T1D investigating the effect of verapamil SR on preservation of beta-cell function. The aim of the study is to confirm recent reports (in a limited number of study participants) that this re-positioned licensed anti-hypertensive agent may have benefits in people with newly diagnosed T1DM.

The Ver-A-Long study is an open-label extension of a multi-centre trial in adult subjects with T1D. It is designed to explore the effect of long-term therapy with 360 mg Verapamil (SR) in those who have been treated with placebo or Verapamil SR for 12 months, on the preservation of beta-cell function over 24 months of treatment.

*Presented by **Martina Brunner** (Senior Project Manager for Clinical Trials, Univ. of Graz)*

• WiNK Therapeutics

A start up biotechnology company ushering in a new way to target cells/tissues for drug development. We utilize modified RNA aptamers to deliver disease-modifying products precisely to the location where they are needed. Our lead products are two individual stands of RNA that specifically deliver signals to the remaining beta islet cells of the pancreas. The first signal instructs the cells to start proliferating, in order to replace the loss beta cell mass. The send signal then causes protective proteins to cover the surface of the beta islet cells, protecting these cells from the autoreactive T-cell attack that is the hallmark of T1D. Thus, these 2 drugs potentially represent a curative treatment for people with T1D.

*Presented by **Warren Marcus** (Founder & CEO)*