INNODIA: open innovation as a European roadmap for disease modifying therapies in type 1 diabetes
Diabetes: a global disease...

Estimated global prevalence of diabetes

- **151 million**
  - 2000
- **366 million**
  - 2011
- **552 million**
  - 2030

Type 1 diabetes

Type 2 diabetes

Type 1 diabetes

= Destruction of beta cells

Therapy: Replacement of all beta cell functions
Replacing all beta-cell functions
If Jenny is diagnosed with T1D at 5 years of age, by the time she is 40, she will have.....

...measured her bloodsugar levels more than 50,000 times and have injected herself with insulin more than 50,000 times....
Achieving glycemic control

Insulin

Exercise

Nutrition

Stress

Stress
Reality
Type 1 diabetes
= Destruction of beta cells

Annex 1 of the Grant Agreement - Description of Action (DoA)

Action Full Title: Translational approaches to disease modifying therapy of type 1 diabetes: An innovative approach towards understanding and arresting Type 1 diabetes

Action Acronym: INNODIA

Grant Agreement no.: 115797
IMI2 Call topic: IMI2-2014-01-01
TRANSLATIONAL APPROACHES TO DISEASE MODIFYING THERAPY OF TYPE 1 DIABETES: AN INNOVATIVE APPROACH TOWARDS UNDERSTANDING AND ARRESTING TYPE 1 DIABETES (INNODIA)

Preclinical type 1 diabetes (T1D) research advanced importantly in recent years, but little progress was made in translating findings from *in vitro* and animal models into effective clinical interventions. INNODIA assembles a comprehensive, complementary consortium of leading clinicians overseeing T1D registries and large clinical trial centres, aligned with basic science experts in beta-cell pathophysiology, immunology, biomarker discovery, bioinformatics, systems biology and trial design. INNODIA will accelerate understanding of T1D via coordinated studies of unique clinical samples and translation-oriented preclinical models delivering novel biomarkers and interventions for testing in appropriately designed trials developed in active collaboration with regulators and patients. INNODIA accesses unique historical biorepositories and will create a clinical EU infrastructure to recruit, deep-phenotype and biosample T1D subjects at diagnosis and at-risk relatives. Participants will be consented to recall, creating a ‘living biobank’. INNODIA will establish an EU-wide collection of pancreas and tissues from T1D and at-risk donors (euPOD, a collaboration with nPOD). Live donor and euPOD samples will undergo high-throughput analyses for established biomarkers and evaluation of novel diagnostics originating from studies in innovative human(ized) *in vitro* and *in vivo* models, within which promising therapeutics will be tested. Clinical and experimental data will follow an integrated pipeline for transverse, multi-dimensional analysis and modelling. Translation of biomarker and therapeutic discovery into clinical interventions will be realized via the INNODIA trial network of clinical centres accredited for interventions in children/adults. In consultation with regulators and patients, novel clinical trial formats will be proposed, enabling small studies and fast data accrual. INNODIA proposes an innovative approach to realize a decisive step towards T1D prevention and cure.
INNODIA

T1D

clinical trials

novel biomarkers

research data

studies

clinical samples

patients

collaboration
Implementing Open Innovation

“... involving far more actors in the innovation process, from researchers, to entrepreneurs, to users, to governments and civil society.”

“We need open innovation to capitalise on the results of European research and innovation. This means creating the right ecosystems, increasing investment, and bringing more companies and regions into the knowledge economy.”

Carlos Moedas, European Commissioner for Research, Science and Innovation - 2016
Patient cohort studies: High risk and newly diagnosed T1D-euPOD

Biomarker Analysis and Validation Core

Novel Models and Mechanistic Studies on T1D Pathogenesis

Management, Exploitation and Dissemination

Systems Biology/In Silico Modelling

Innovative Clinical Trials in EU

Advisory Boards (Strategic and ethics)

Associates (nPOD, EURADIA, Enpr-EMA)

WP1
WP2
WP3
WP4
WP5
WP6

WP6 Management, Exploitation and Dissemination

WP4 Systems Biology/In Silico Modelling

WP5 Innovative Clinical Trials in EU

WP3 Novel Models and Mechanistic Studies on T1D Pathogenesis

WP1 Patient cohort studies: High risk and newly diagnosed T1D-euPOD

Organisation of INNODIA
WP1  Patient cohort studies: High risk and newly diagnosed T1D-euPOD

WP2  Biomarker Analysis and Validation Core

WP3  Novel Models and Mechanistic Studies on T1D Pathogenesis

WP4  Systems Biology/In Silico Modelling

WP5  Innovative Clinical Trials in EU

WP6  Management, Exploitation and Dissemination

Advisory Boards (Strategic and ethics)

Associates (nPOD, EURADIA, Enpr-EMA)

Organisation of INNODIA
17 INNODIA partner sites

Local network
(e.g. UK, D, I, DK, F, FI)

1500
newly diagnosed T1D,
<6 weeks from diagnosis
2 years follow up

3000
unaffected family members
(300 Autoantibody+)
4 year follow up

www.innodia.eu
Patient cohort studies: High risk and newly diagnosed T1D-euPOD

WP2 Biomarker Analysis and Validation Core

WP3 Novel Models and Mechanistic Studies on T1D Pathogenesis

WP6 Management, Exploitation and Dissemination

WP4 Systems Biology/In Silico Modelling

WP5 Innovative Clinical Trials in EU

Advisory Boards (Strategic and ethics)

Associates (nPOD, EURADIA, Enpr-EMA)

Organisation of INNODIA
WP1/2 map

- WP1 clinical centres
- Primary hub (fresh cell assays)
- Secondary hub (frozen PBMC)
- 24h shipment
- <6h shipment
Organisation of INNODIA

WP1 Patient cohort studies: High risk and newly diagnosed T1D-euPOD

WP2 Biomarker Analysis and Validation Core

WP4 Systems Biology/In Silico Modelling

WP5 Innovative Clinical Trials in EU

WP6 Management, Exploitation and Dissemination

WP3 Novel Models and Mechanistic Studies on T1D Pathogenesis

Advisory Boards (Strategic and ethics)

Associates (nPOD, EURADIA, Enpr-EMA)
WP1 Patient cohort studies: High risk and newly diagnosed T1D-euPOD

WP2 Biomarker Analysis and Validation Core

WP3 Novel Models and Mechanistic Studies on T1D Pathogenesis

WP4 Systems Biology/In Silico Modelling

WP5 Innovative Clinical Trials in EU

WP6 Management, Exploitation and Dissemination

Advisory Boards (Strategic and ethics)

Associates (nPOD, EURADIA, Enpr-EMA)

Organisation of INNODIA
eCRF Consultation process & Data upload/QC

Clinical sites
- Specs collection
- Testing
- Training

Central labs
- specs collection
- Testing
- Training

UCPH INNODIA Project team

Data providers
- Data upload

Communication & reports
Consortium leader
Programme Manager
INNODIA Policy Making

INNODIA Database

Implementation
WP1 Patient cohort studies: High risk and newly diagnosed T1D-euPOD

WP2 Biomarker Analysis and Validation Core

WP3 Novel Models and Mechanistic Studies on T1D Pathogenesis

WP4 Systems Biology/In Silico Modelling

WP5 Innovative Clinical Trials in EU

WP6 Management, Exploitation and Dissemination

Advisory Boards (Strategic and ethics)

Associates (nPOD, EURADIA, Enpr-EMA)
Description of the work in first 12-18 months

Who does what?

To establish a step change in the way we evaluate novel T1D therapeutics in collaboration with regulators and EFPIA partners

Clinical trial network (CTN)

- D5.1 An accreditation system for clinical trial centers in T1D prevention and intervention inside the EU (M12)
- D5.2 A network of accredited clinical trial centers (adult and paediatric) in the EU accessible for T1D interventions (M24)

Clinical trial design

- D5.3 Clinical trial design for a phase II study with results from a simulation study to demonstrate the operating characteristics (M36)
- D5.4 Computer code that can be run quickly to produce interim analysis reports during the phase II trial(s) (M42)

5.5. To perform at least one novel innovative phase II clinical trial within the accredited European paediatric and adult clinical INNODIA trial network established in 5.1 (HKA (Darrie), UCAM (Dunger), MRC (Mander), KU Leuven (Mathieu), GSK, Sanofi, Eli Lilly, Novo)
INNODIA ACCREDITATION VISIT PROGRAMME 2016/2017

Handbook for the
INNODIA Accreditation Visit Programme

General information about INNODIA can be found on http://www.INNODIA.eu/.
Implementing Open Innovation

“… involving far more actors in the innovation process, from researchers, to entrepreneurs, to users, to governments and civil society.”

“We need open innovation to capitalise on the results of European research and innovation. This means creating the right ecosystems, increasing investment, and bringing more companies and regions into the knowledge economy.”

Carlos Moedas, European Commissioner for Research, Science and Innovation - 2016
Organisation of INNODIA

WP1 Patient cohort studies: High risk and newly diagnosed T1D-euPOD

WP2 Biomarker Analysis and Validation Core

WP3 Novel Models and Mechanistic Studies on T1D Pathogenesis

WP4 Systems Biology/In Silico Modelling

WP5 Innovative Clinical Trials in EU

WP6 Management, Exploitation and Dissemination

Advisory Boards (Strategic and ethics)

Associates (nPOD, EURADIA, Enpr-EMA)

Patient Advisory Committee (patients and families from different countries, IDF-Europe)
Patient cohort studies: High risk and newly diagnosed T1D-euPOD

Biomarker Analysis and Validation Core

Novel Models and Mechanistic Studies on T1D Pathogenesis

System Biology/In Silico Modelling

Innovative Clinical Trials in EU

Management, Exploitation and Dissemination

Advisory Boards (Strategic and ethics)

Associates (nPOD, EURADIA, Enpr-EMA)

WP1
WP2
WP3
WP4
WP5
WP6

Organisation of INNODIA

Patient Advisory Committee (patients and families from different countries, IDF-Europe)
Patient Advisory Committee

Anders

Nathalie

Jaivir

Markku

Olivier

Kyle

Jente and Dries

Johan
WELCOME TO INNODIA

Translational approaches to disease modifying therapy of type 1 diabetes: an innovative approach towards understanding and arresting type 1 diabetes

www.innodia.eu
Clinical Centres for patients and relatives

How can I participate?

<table>
<thead>
<tr>
<th>Flag</th>
<th>Country</th>
<th>Name</th>
<th>City</th>
<th>Pediatric</th>
<th>Adult</th>
</tr>
</thead>
<tbody>
<tr>
<td>🇦🇹</td>
<td>Austria</td>
<td>Medical University of Graz</td>
<td>Graz</td>
<td></td>
<td></td>
</tr>
<tr>
<td>🇧🇪</td>
<td>Belgium</td>
<td>UZ Gasthuisberg</td>
<td>Leuven</td>
<td></td>
<td></td>
</tr>
<tr>
<td>🇩🇰</td>
<td>Denmark</td>
<td>Herlev University Hospital, Region Hovedstaden</td>
<td>Herlev</td>
<td></td>
<td></td>
</tr>
<tr>
<td>🇱🇺</td>
<td>Luxembourg</td>
<td>Centre Hospitalier de Luxembourg Clinique pediatrique Kannerklinik</td>
<td>Luxembourg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>🇵🇱</td>
<td>Poland</td>
<td>Śląski Uniwersytet Medyczny Katowice</td>
<td>Katowice</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Focus of PAC action on Clinical Centers help for having the maximum participation of Patients and family relatives

- Elaboration of multimedia material
  - Videos for Clinical Centres - Testimonies / Information
  - Innodia « Webmap » Centres for Patients and Relatives
  - Booklet for Kids
  - Innodia website Patient area improvement
  - Social Media strategy elaboration – Communication group

- Advise for handout / posters documents written in « Lay language »

- Support to « day on site » organized by the Centers
  *Live testimonies of by PAC members having participated to clinical trials*
Nearly 120 INNODIA participants recently gathered in Leuven for their first annual meeting to review and discuss the progress and the work ahead. Watch INNODIA participants and patient representatives share their expectations, ambitions and visions for the project.

https://www.youtube.com/watch?v=9SkJEQ3hJmpA

https://www.youtube.com/embed/d7KM3EjDHQY

INNODIA Kyle Ross diabetes
Target audience:
- Patients
- Relatives of patients
- Interested citizens
- Researchers

Aims:
- To raise awareness about INNODIA
- To participate in the T1D community
- To raise awareness about T1D

<table>
<thead>
<tr>
<th>Social Media tool</th>
<th>Target group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facebook</td>
<td>Patient community, relatives, interested citizens</td>
</tr>
<tr>
<td>Twitter</td>
<td>Patient community, relatives</td>
</tr>
<tr>
<td>LinkedIn</td>
<td>Researchers, collaborator</td>
</tr>
<tr>
<td>Instagram</td>
<td>Younger patient community</td>
</tr>
</tbody>
</table>
Translating INNODIA to the public
Implementing Open Innovation

“... involving far more actors in the innovation process, from researchers, to entrepreneurs, to users, to governments and civil society.”

“We need open innovation to capitalise on the results of European research and innovation. This means creating the right ecosystems, increasing investment, and bringing more companies and regions into the knowledge economy.”

Carlos Moedas, European Commissioner for Research, Science and Innovation
Thank you

Chantal Mathieu, MD PhD

chantal.mathieu@uzleuven.be

www.innodia.eu
@innodia

www.imi.europa.eu
@IMI_JU