

# **INNODIA: open innovation as a European roadmap for disease modifying therapies in type 1 diabetes**

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# Diabetes: a global disease...

## Estimated global prevalence of diabetes



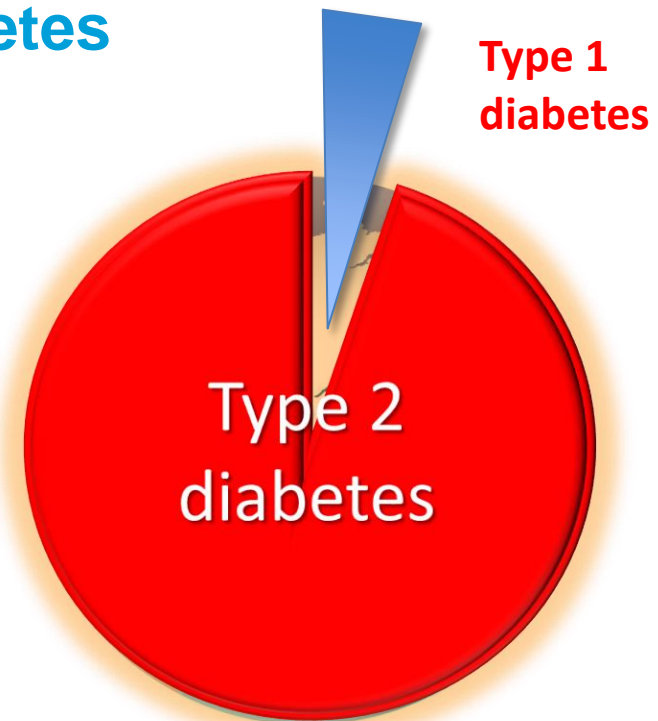
**151 million**

**2000**



**366 million**

**2011**

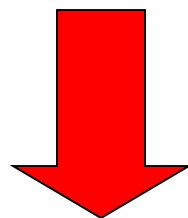


**552 million**

**2030**

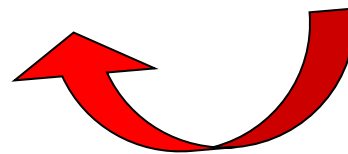
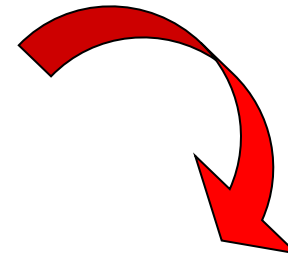
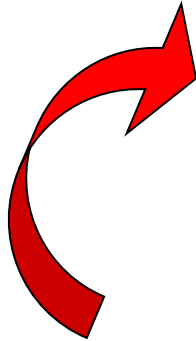
International Diabetes Federation. IDF Diabetes Atlas. Fourth Edition. 2010

Type 1 diabetes  
= Destruction of beta cells



Therapy: Replacement of all  
beta cell functions

# Replacing all beta-cell functions



# Type 1 diabetes



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

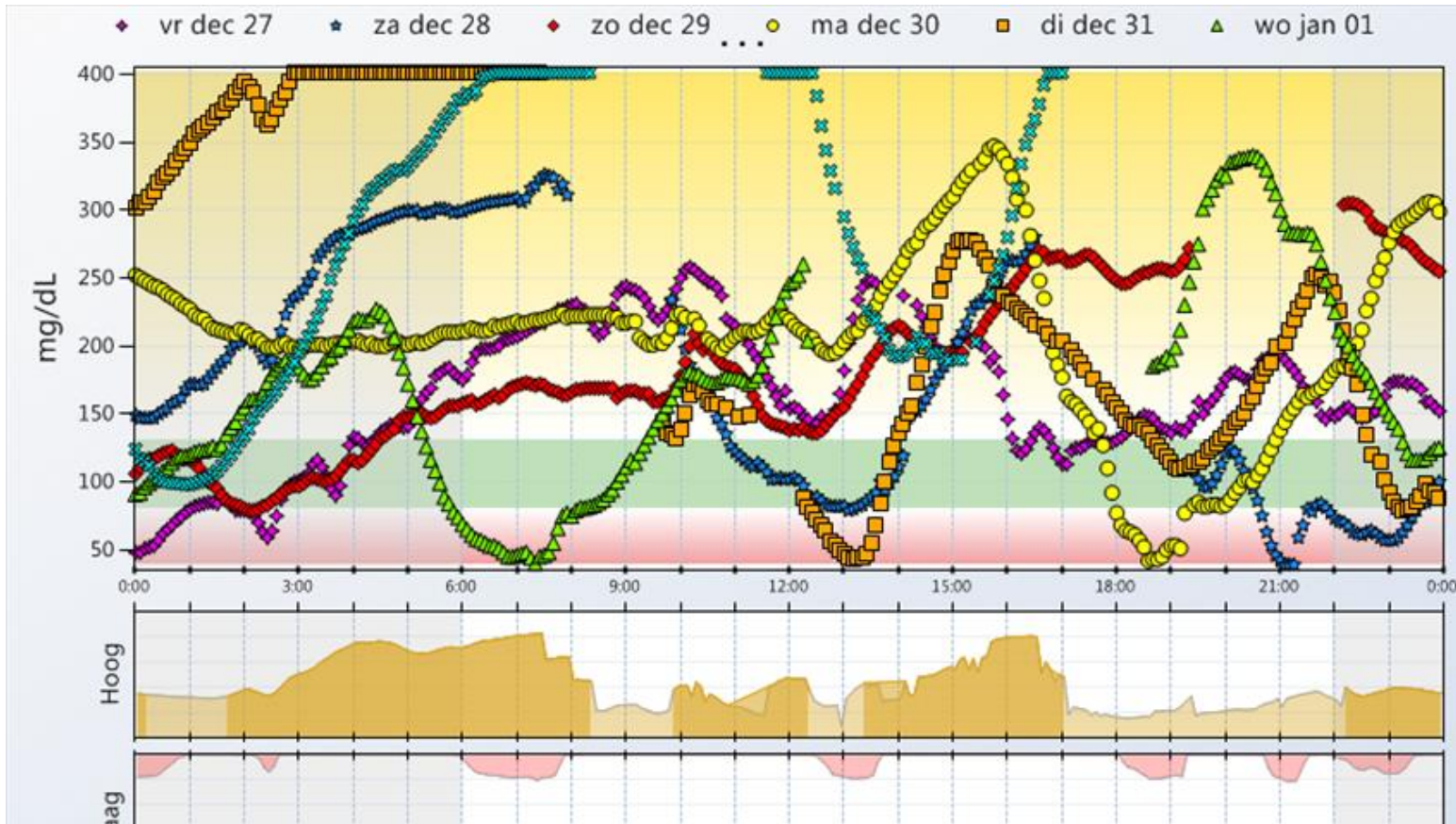
Exercise

Stress



Nutrition

Stress

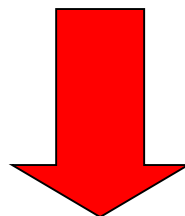


Sta
Gemiddelde glucose
Sensorgebruik
Kalibraties/dag
Standaardafwijking
Streefbereik 's Nachts

Inte



# Type 1 diabetes = Destruction of beta cells



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

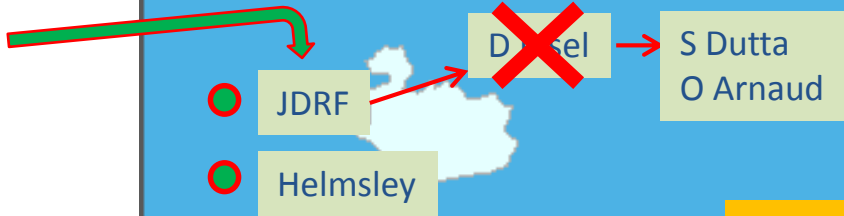
Action Full Title: Translational approaches to disease modifying therapy of type 1 diabetes: An innovative approach towards understanding and arresting Type 1 diabetes

Action Acronym: INNODIA

Grant Agreement no.: 115797  
IMI2 Call topic: IMI2-2014-01-01



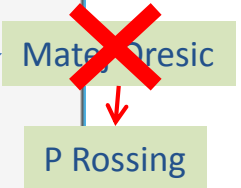




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Francesco Dotta, UNISI, Siena  
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Francesco Chiarelli, UD'A, Chieti

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Carine de Beaufort, CHL, Luxembourg

# 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 bio-sample 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.



## Implementing Open Innovation



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

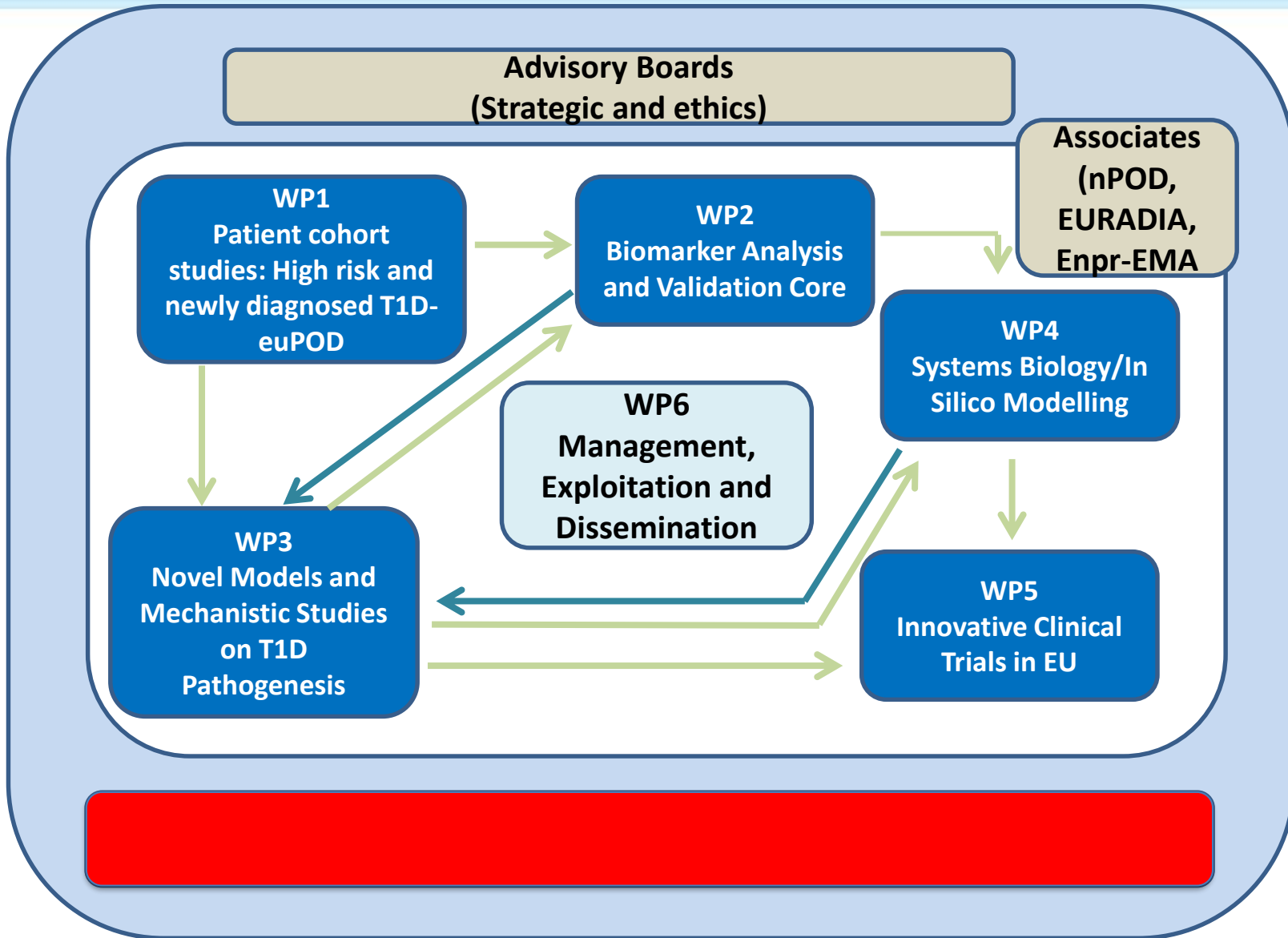
“We need open innovation to capitalise on the results of European research and innovation. This means creating the right ecosystems, increasing investment, and bringing more companies and regions into the knowledge economy.”

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

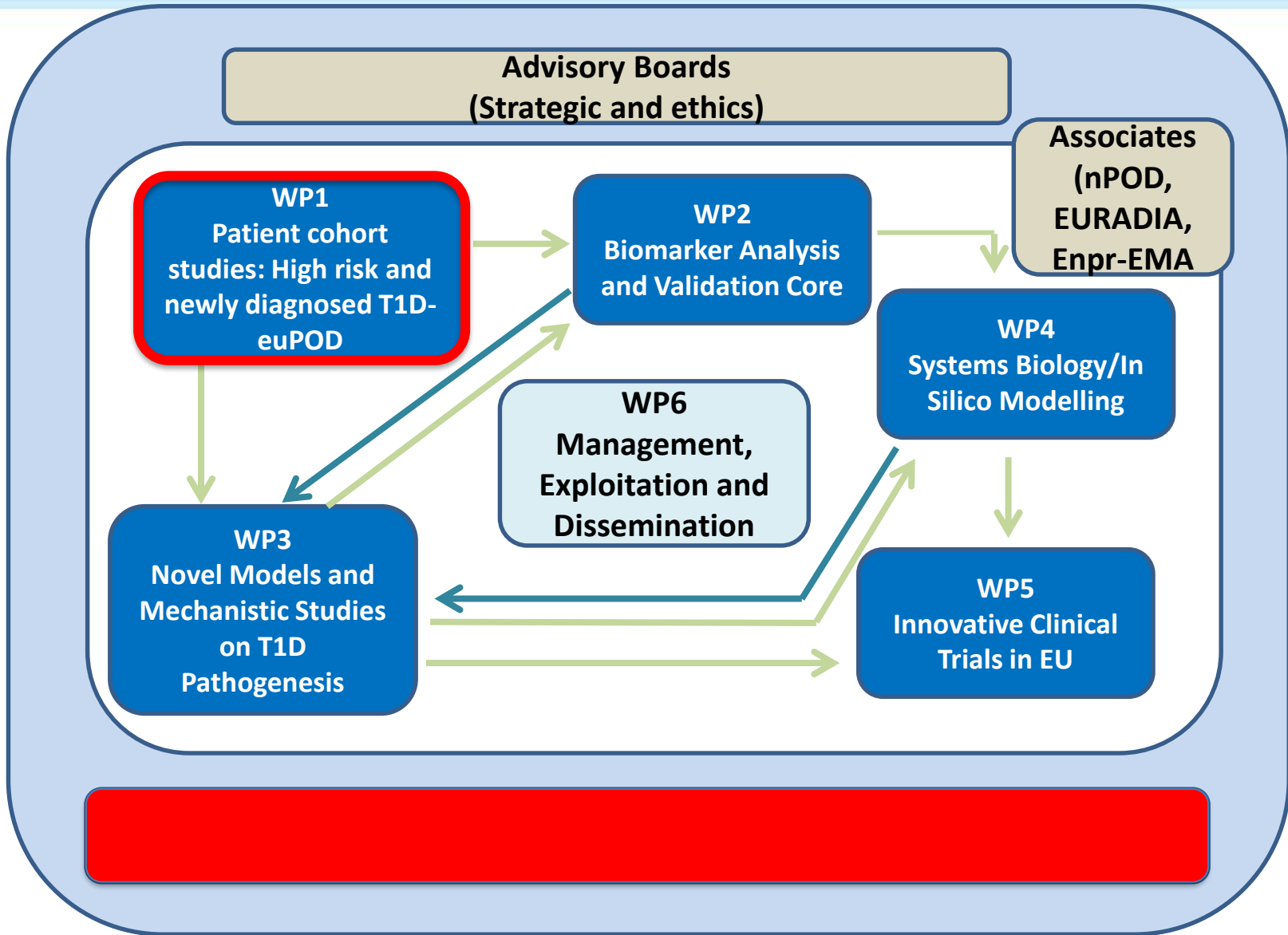


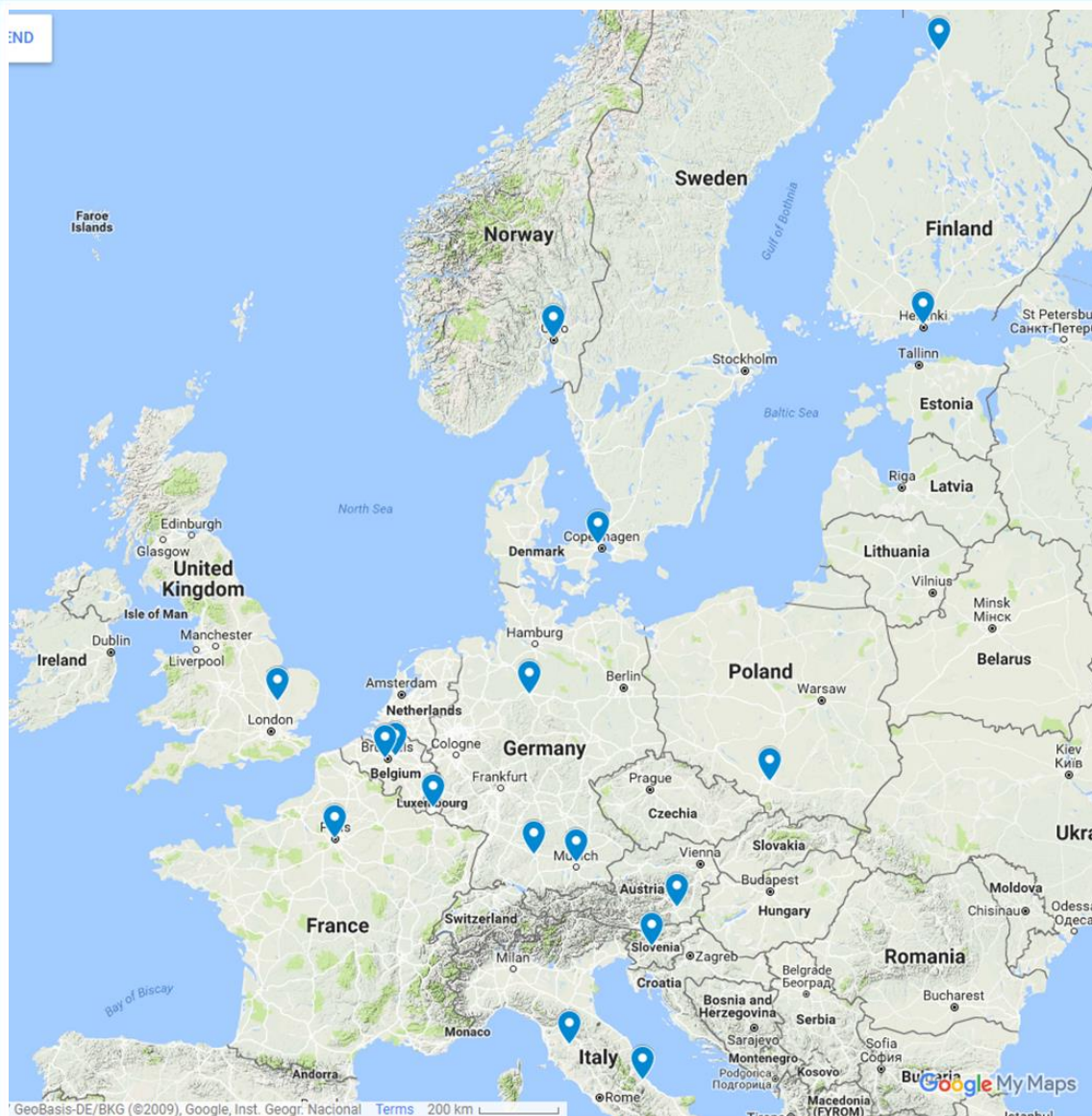
innovative  
medicines  
initiative

# Organisation of INNODIA



# 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

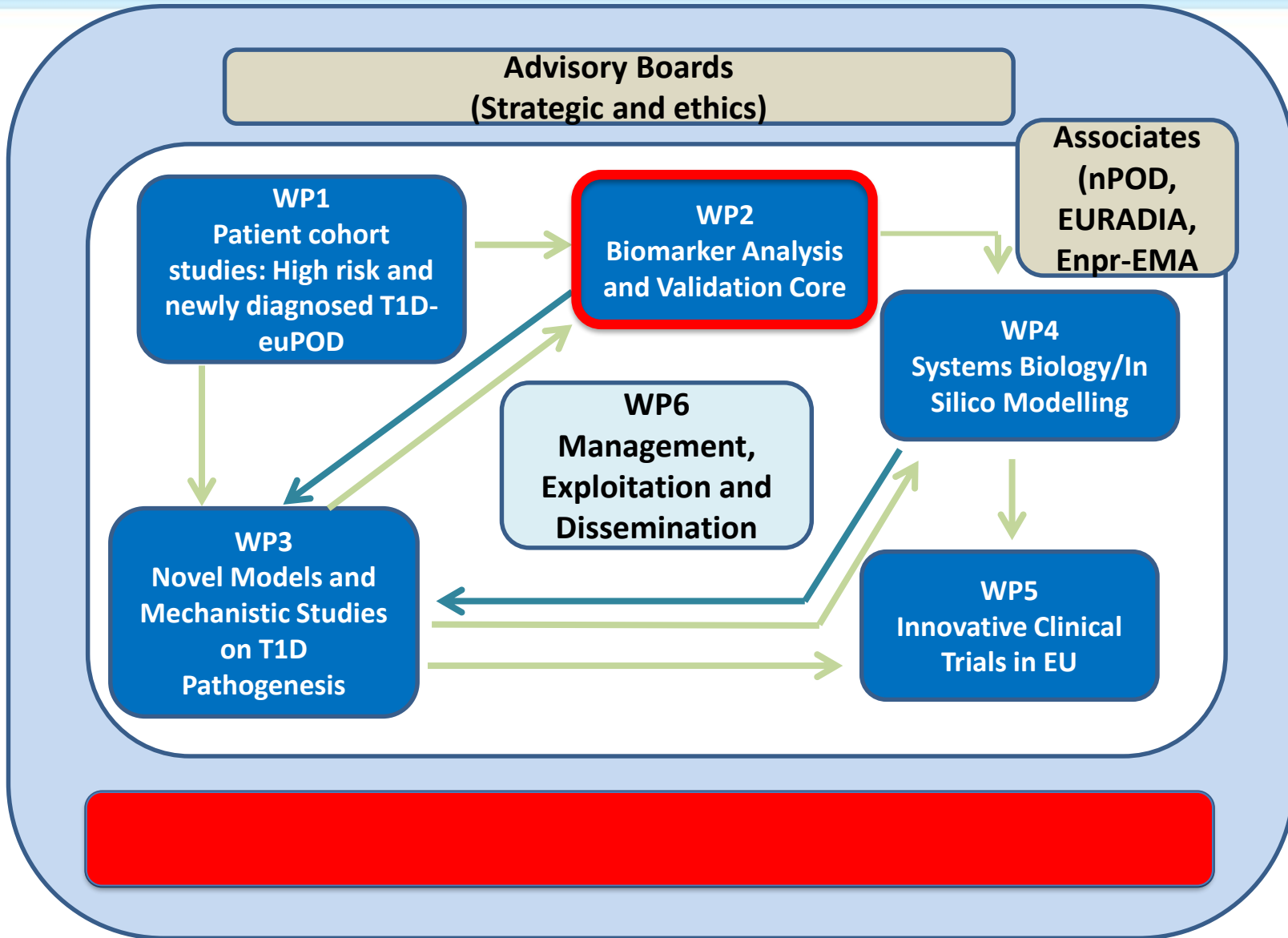
**3000**

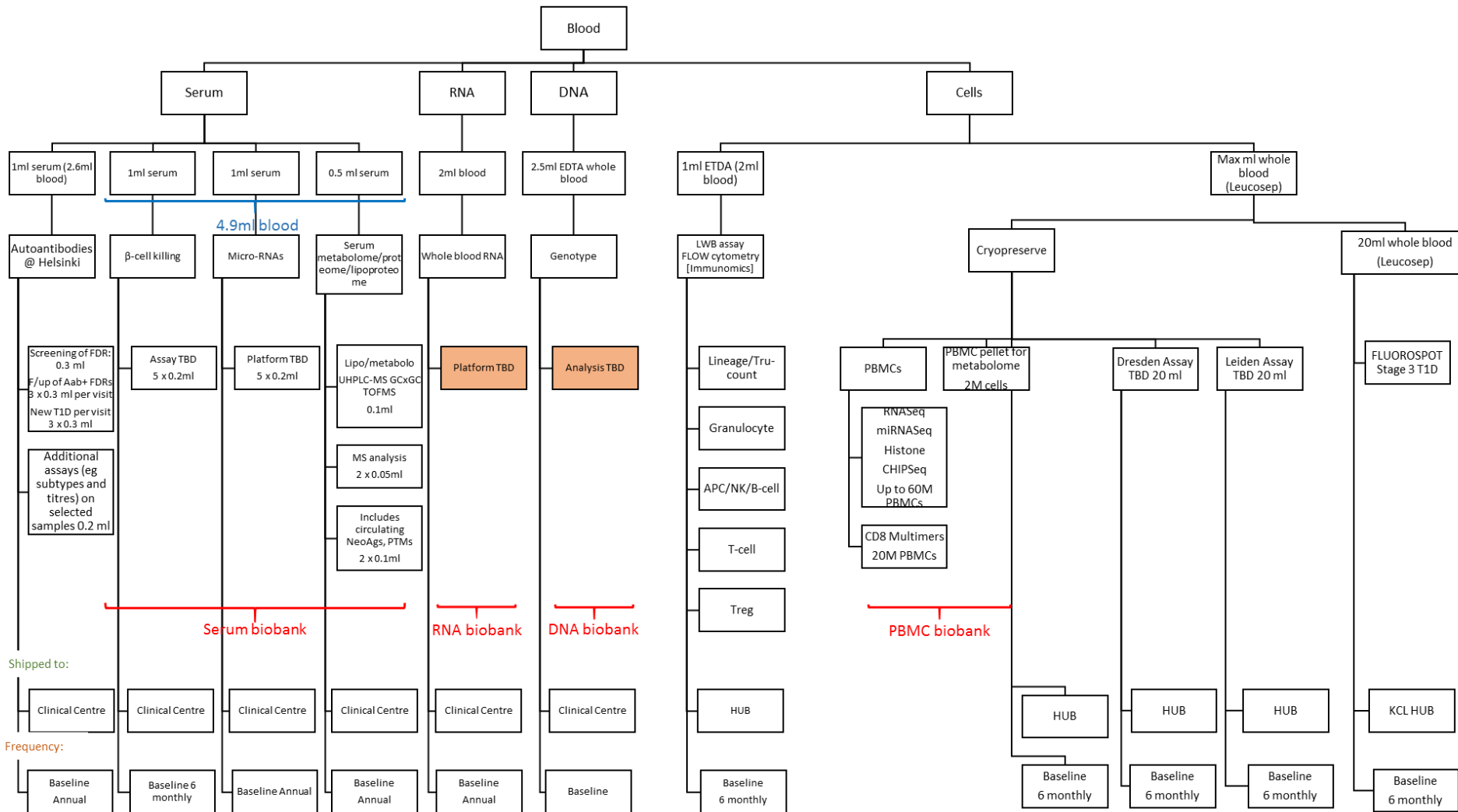
unaffected family members  
(300 Autoantibody +)  
4 year follow up

[www.innodia.eu](http://www.innodia.eu)

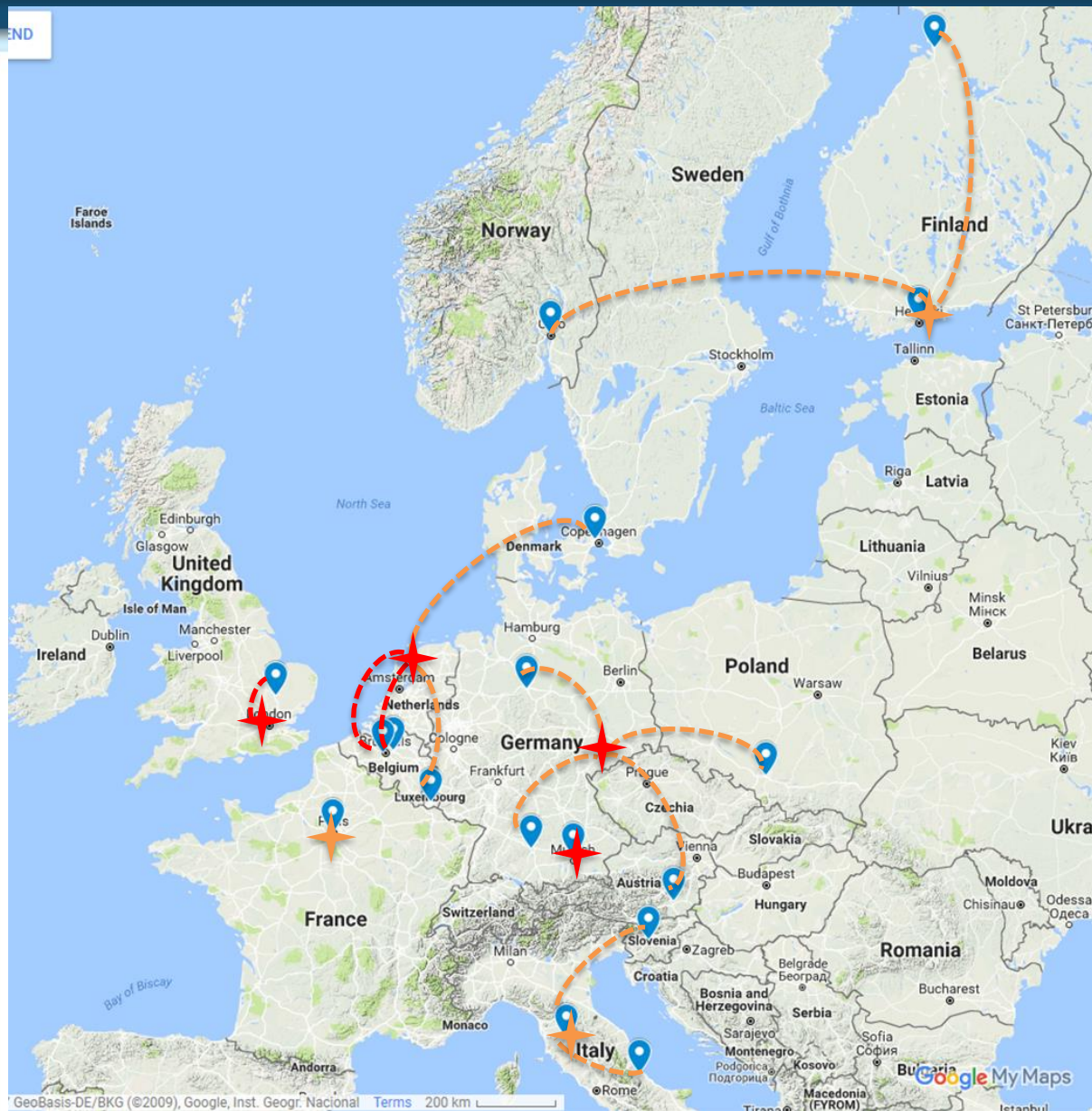


# Organisation of INNODIA





# WP1/2 map



WP1 clinical centres

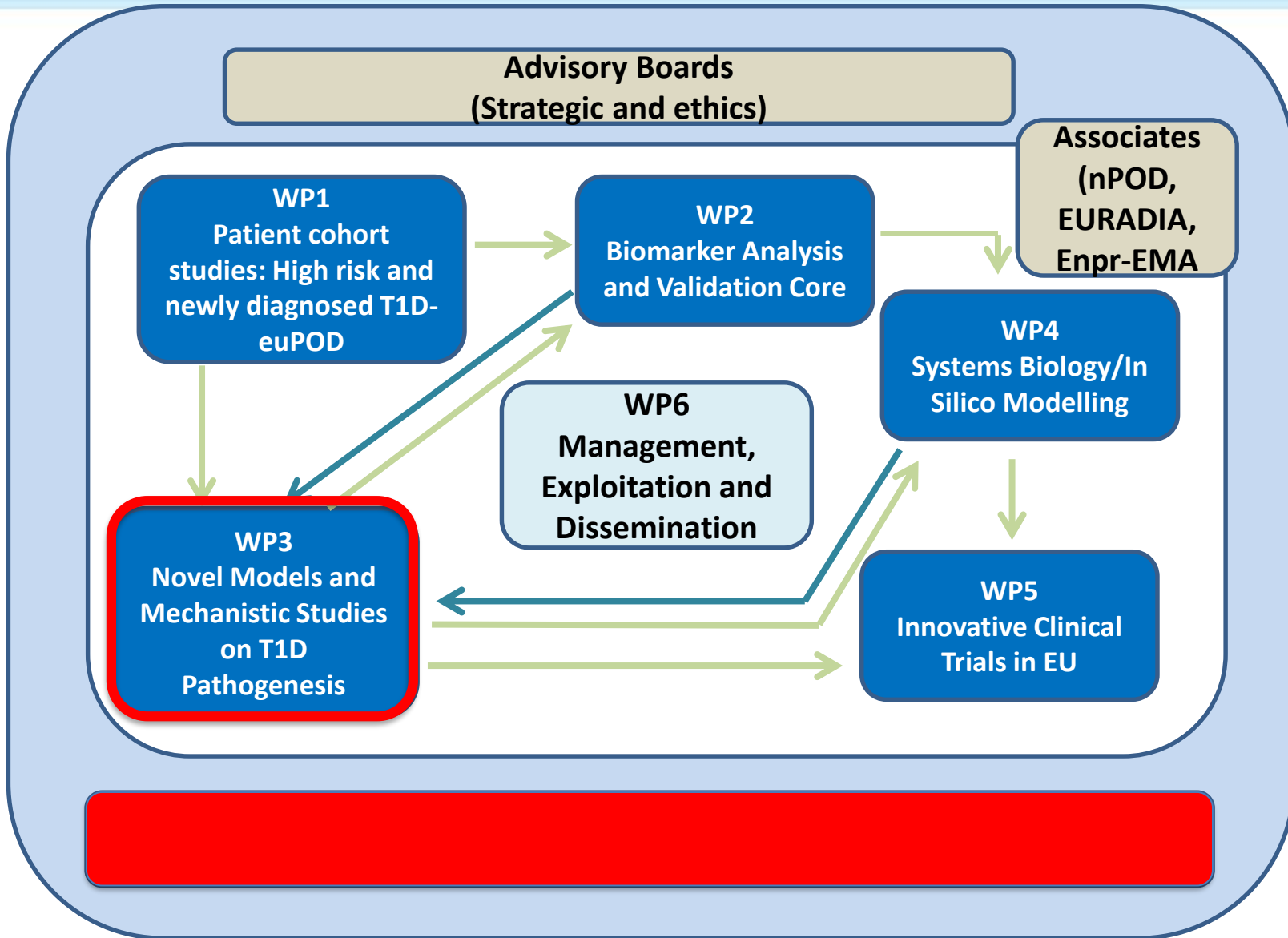
Primary hub  
(fresh cell assays)

Secondary hub  
(frozen PBMC)

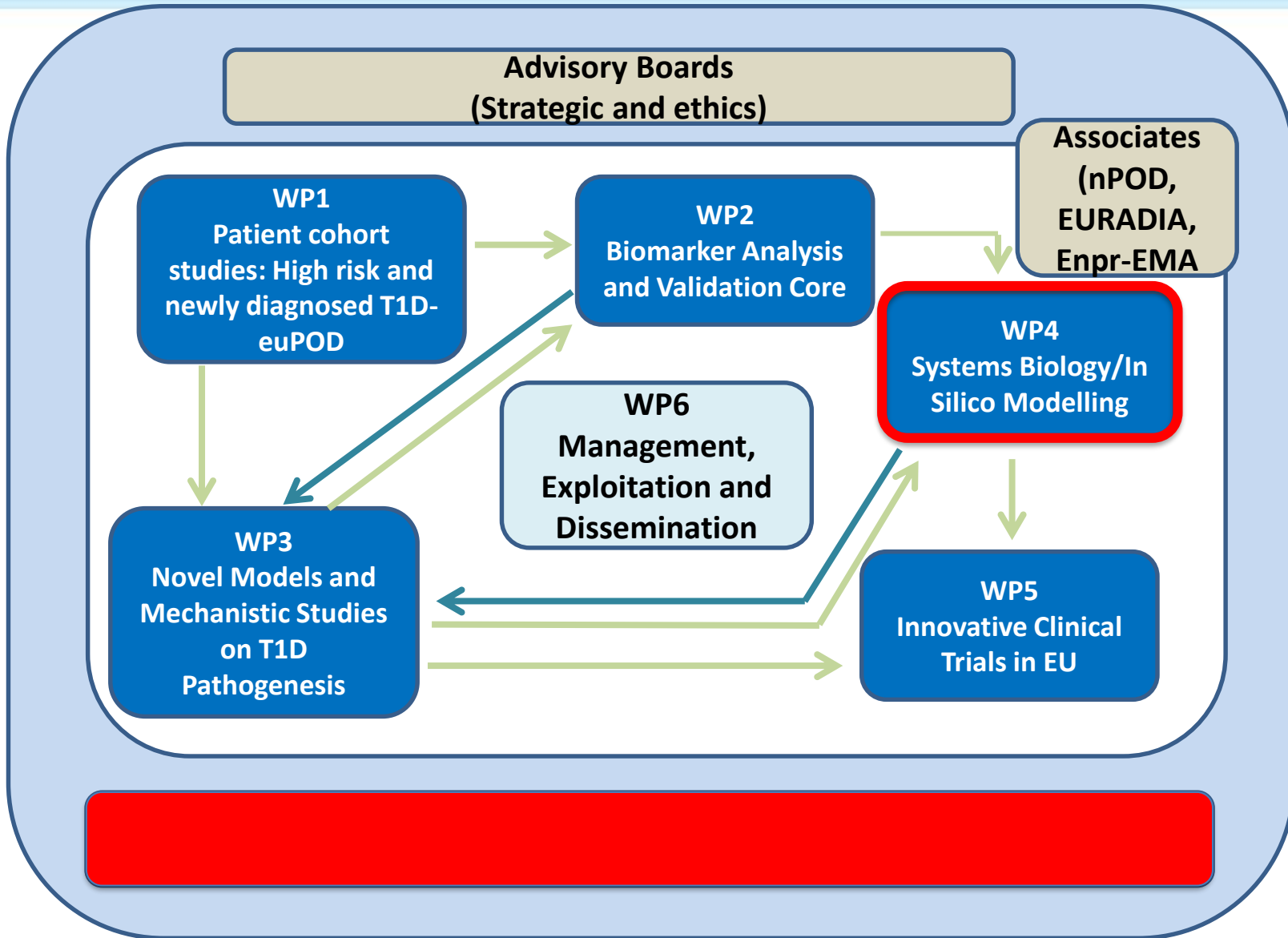
24h shipment

<6h shipment

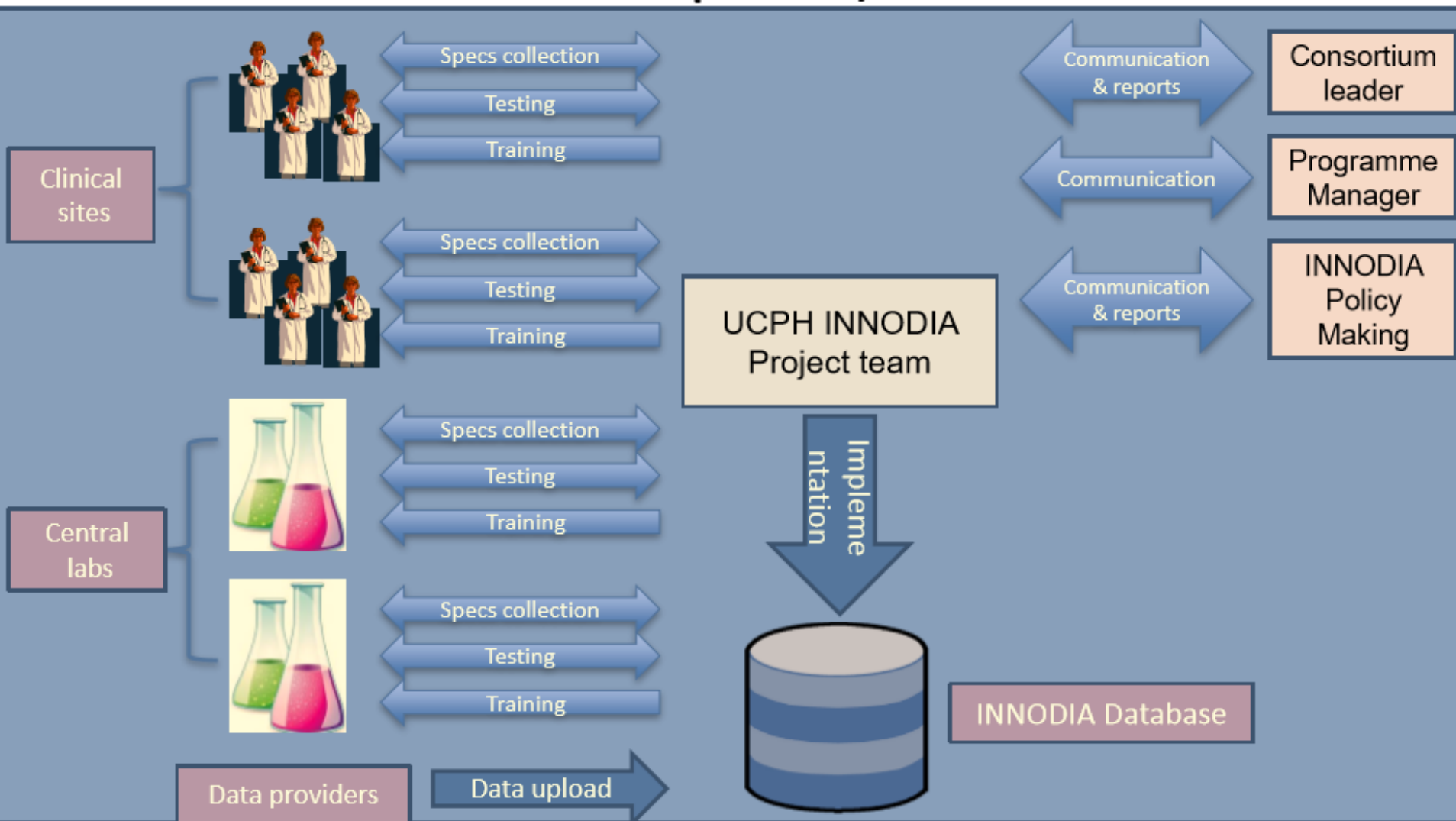
# Organisation of INNODIA



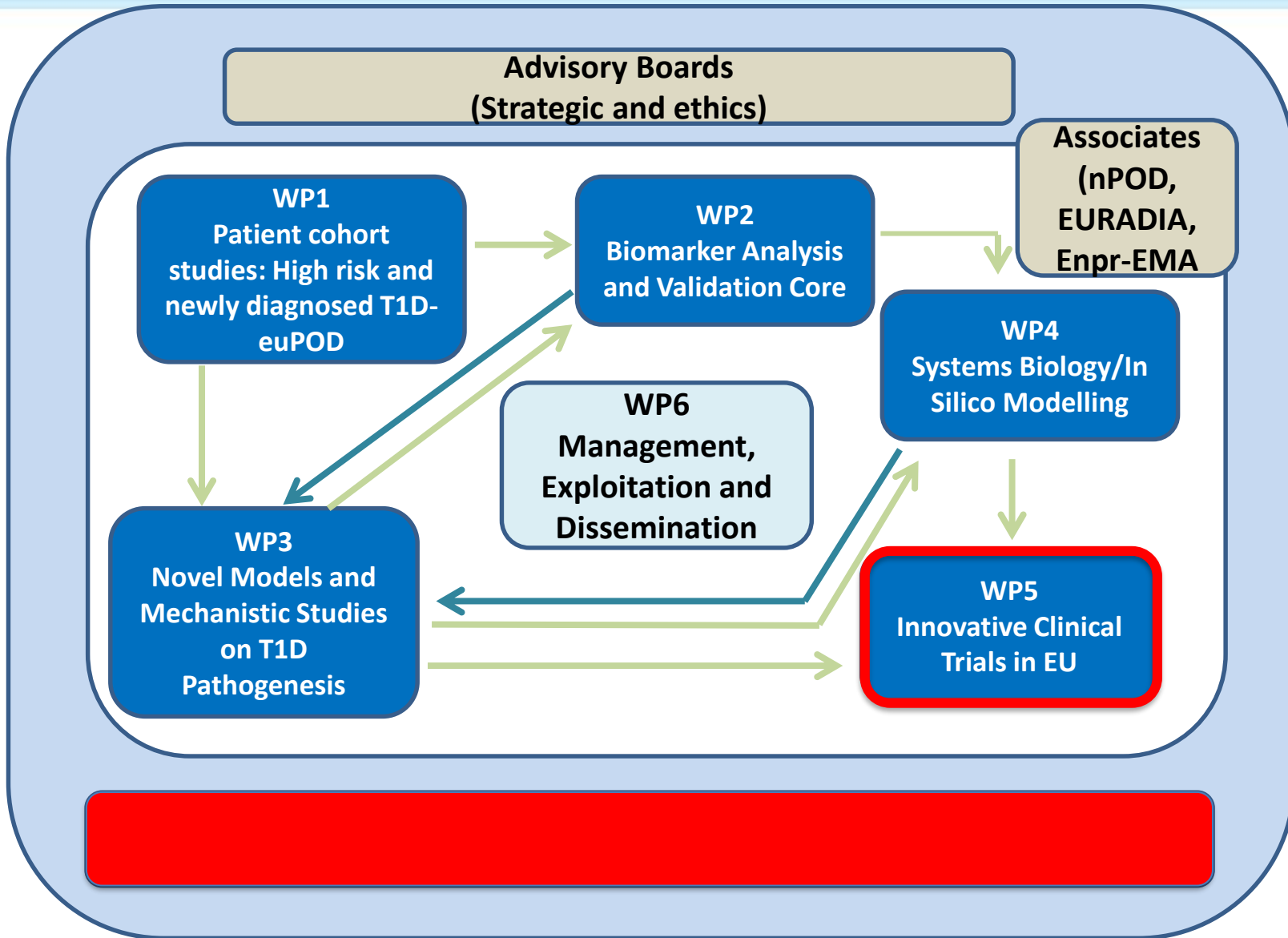
# Organisation of INNODIA



# eCRF Consultation process & Data upload/QC



# Organisation of INNODIA



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 (Danne), 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



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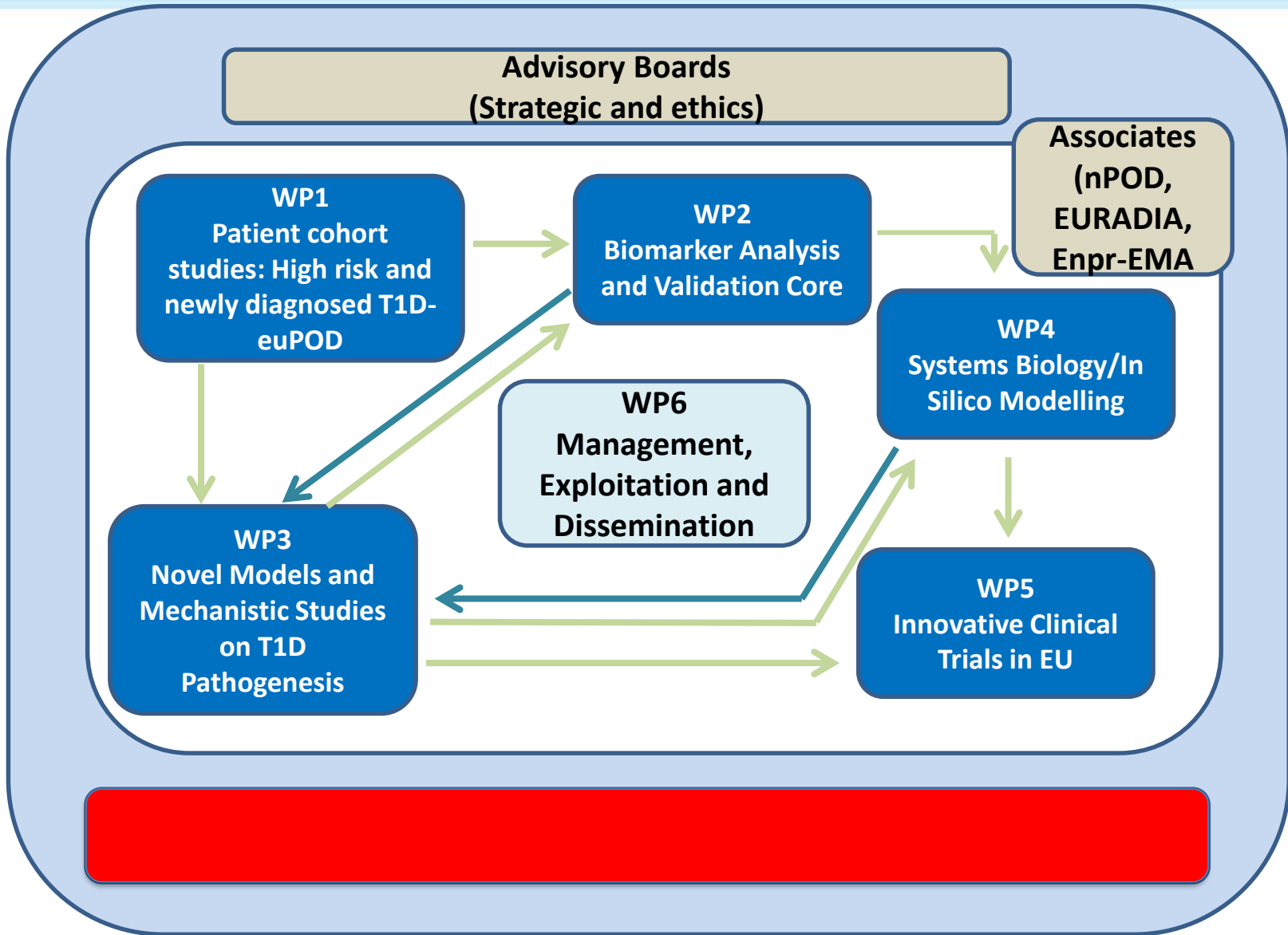
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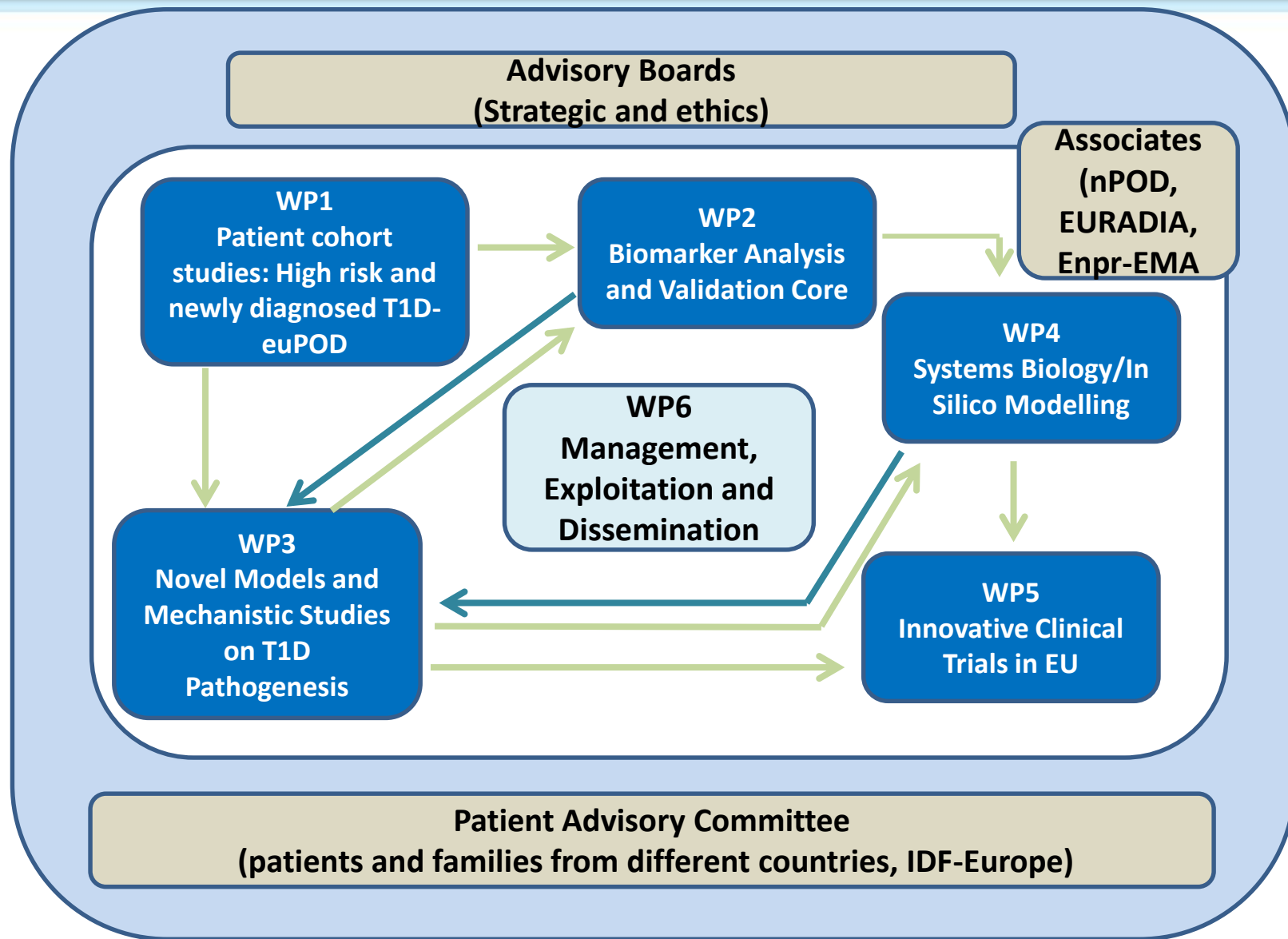


innovative  
medicines  
initiative

# Organisation of INNODIA



# Organisation of INNODIA



# Patient Advisory Committee

Anders



Nathalie

Olivier



Markku



Jaivir



Kyle



Jente and Dries



Johan

[HOME](#)[CONSORTIUM](#)[PARTNERS](#)[PATIENTS](#)

iNNODIA

A PRIVATE PUBLIC PARTNERSHIP  
AGAINST TYPE 1 DIABETES[PUBLICATIONS](#)[NEWS](#)[LINKS](#)[CONTACT](#)[MEMBERS AREA](#)

# 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](http://www.innodia.eu)

# INNODIA WEBSITE: recruitment information

## Clinical Centres for patients and relatives How can I participate ?

Home

### Centers

Search center

Map



Flag	Country	Name	City	Pediatric	Adult
	Austria	Medical University of Graz	Graz		
	Belgium	UZ Gasthuisberg	Leuven		
	Denmark	Herlev University Hospital, Region Hovedstaden	Herlev		
	Luxembourg	Centre Hospitalier de Luxembourg Clinique pediatrique Kannerklinik	Luxembourg		
	Poland	Śląski Uniwersytet Medyczny Katowice	Katowice		

[www.innodia.eu](http://www.innodia.eu)

## 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*





# Patient Advisory Committee



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 sharing their expectations, ambitions and visions for the project.



<https://www.youtube.com/watch?v=93dAQ2lmpA>



<https://www.youtube.com/embed/o7kMMEJDHQY>





## 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**



Social Media tool	Target group
Facebook	Patient community, relatives, interested citizens
Twitter	Patient community, relatives
LinkedIn	Researchers, collaborator
Instagram	Younger patient community

# Translating INNODIA to the public



# iNNOVIA

iNNOVIA

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



elpia

JDRF

HEMSLEY



# Thank you

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[www.innodia.eu](http://www.innodia.eu)

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 @IMI\_JU