

Successful IMI project: INNODIA



2nd June 2016

Professor David Dunger
Department of Paediatrics



Summary of activities EUCADET

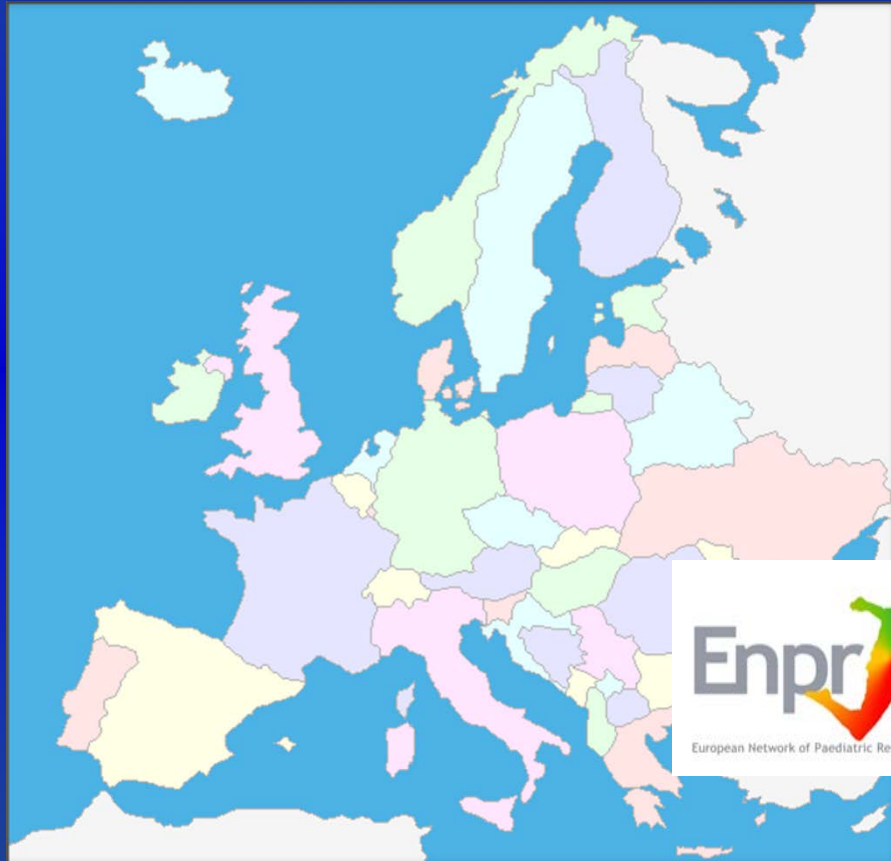
- 26th November 2011, EnprEMA meeting to set up new networks, EMA Head Office, London
- 25th May 2012 and 21st September 2012, workshops to initiate the network involving industry and academia.
- 2012, Full support from the European Society for Paediatric Endocrinology and the International Society for Paediatric and Adolescent Diabetes
- Workshop at the EMA Paediatric/adolescent T2D Workshop
25th February 2013 Paediatric investigation plans in type 2 diabetes mellitus. Scoping of T2D registries
- 2014 Diabetes Care paper *Joining Forces: A call for Greater Collaboration to study New Medicines in Children and Adolescents with Type 2 Diabetes* Janina Karres , Valerie Pratt , Jean-Marc Guettier, Jean Temeck , William V. Tamborlane , David Dunger, Cristina Bejnariu , Carine De Beaufort, Paolo Tomasi
Diabetes Care 2014;37:2665–2667

European Children and Adolescent Diabetes and Endocrinology Clinical Trials network (EUCADET)

Steering Committee meeting

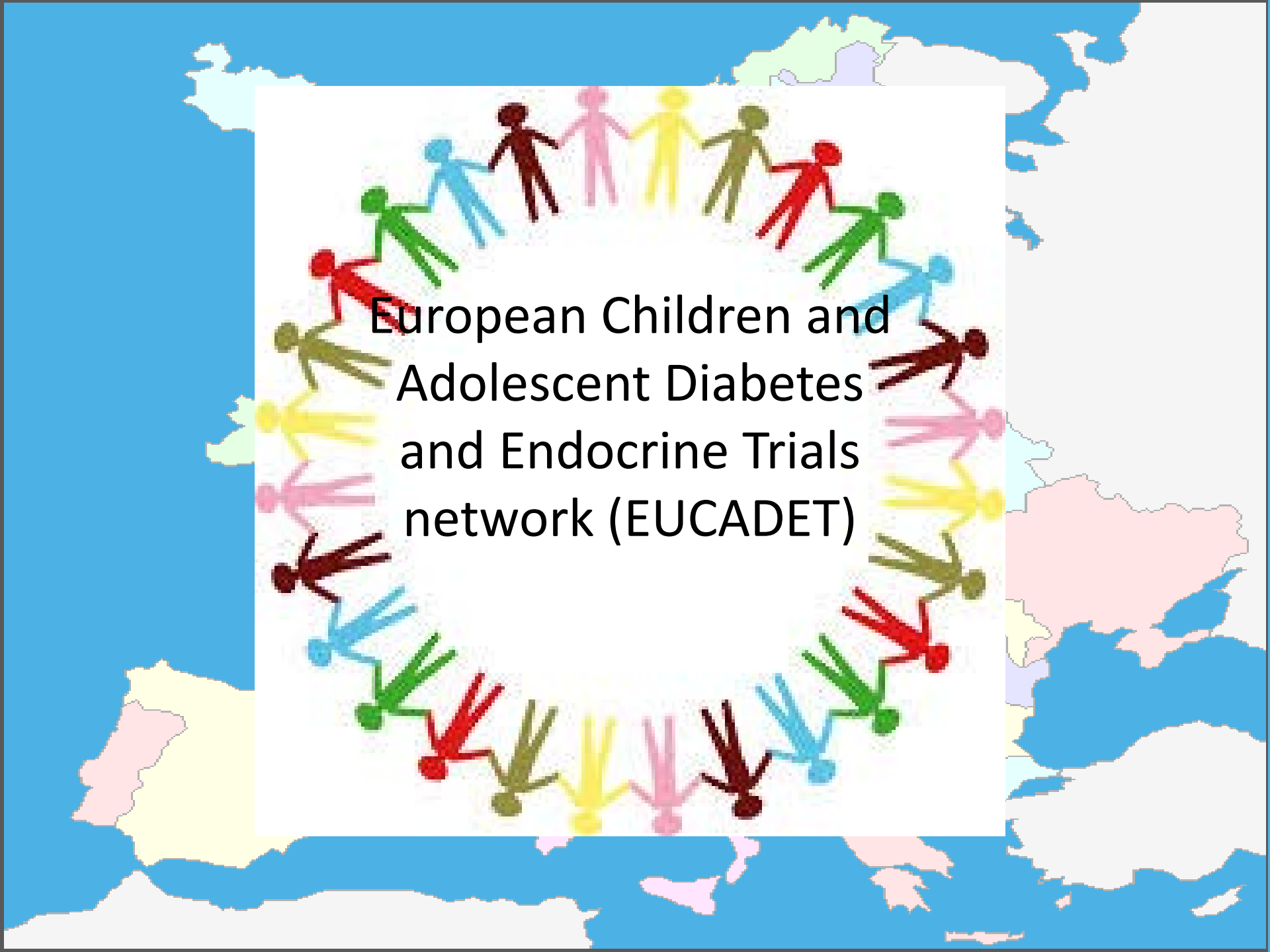
MRC Head Office London

10th February 2015



**Coordinators: Professor David Dunger - University of Cambridge
Professor Mehul Dattani - University College London**



The image features a central white rectangular area containing a circular arrangement of approximately 25 colorful stick figures. Each figure is a simple, stylized human form in a different color (including red, green, blue, yellow, brown, pink, and purple). They are all holding hands, forming a continuous ring. This central graphic is superimposed on a background that is a stylized world map. The map uses various colors to represent different continents and regions, with a prominent blue area on the left side. The overall composition is clean and modern, with a focus on global unity and diversity.

European Children and
Adolescent Diabetes
and Endocrine Trials
network (EUCADET)

Summary of activities

- 26th November 2011, EnprEMA meeting to set up new networks, EMA Head Office, London
- 25th May 2012 and 21st September 2012, workshops to initiate the network involving industry and academia.
- 2012, Full support from the European Society for Paediatric Endocrinology and the International Society for Paediatric and Adolescent Diabetes
- Workshop at the EMA Paediatric/adolescent T2D Workshop
25th February 2013 Paediatric investigation plans in type 2 diabetes mellitus. Scoping of T2D registries
- Approach to Efpia re IMI call and need for a European Endocrine Diabetes paediatric clinical network



Innovative Medicines Initiative

1st Call for Proposals 2014

Innovative Medicines Initiative 2

Version 3.3

7 years

TABLE OF CONTENTS

INTRODUCTION	2
1. TRANSLATIONAL APPROACHES TO DISEASE MODIFYING THERAPY OF TYPE 1 DIABETES MELLITUS (T1DM)	4
2. DISCOVERY AND VALIDATION OF NOVEL ENDPOINTS IN DRY AGE-RELATED MACULAR DEGENERATION AND DIABETIC RETINOPATHY	15
CONDITIONS FOR THIS CALL	22







IMI2 Call -Translational approaches to disease modifying therapy of type 1 diabetes mellitus (T1DM)

- **The T1DM program in IMI2 invites applicant consortia to build a cross-functional research initiative with the objective to launch a program that could lead to prevention as well as T1DM disease modifying and ultimately to a curative therapy in the future.**
- **To achieve this ambitious goal deeper insight to the heterogeneous, phenotypical characteristics of people either at risk of developing T1DM or having manifest disease is required.**
- **Using state of the art technologies it is envisioned that the successful consortium will focus on a complete mapping of interactions between the immune system and pancreatic beta cells in humans and on the environmental changes that has led to increased disease incidence.**
- **The programs should embrace a strong focus on translational medical activities initiated at the bedside, refined at the workbench, and then finally brought back to the bedside for clinical validation of potential therapeutic approaches aiming at fundamentally preventing, halting, and reversing the β -cell destructive course of T1DM.**

Unique opportunity to really tackle type 1 diabetes: From basic research to clinic, novel therapeutics clinical trial design and new surrogate biomarkers of disease progression



Natural Immunomodulators as
Novel Immunotherapies for
Type 1 Diabetes



Chantal Mathieu
Klaus Badenhoop
Polly Bingley
Colin Dayan
Jocelyne Demengeot
Francesco Dotta
Decio Eizirik
Sigurd Lenzen
Pierro Marchetti
Mark Peakman
Bart Roep
Jaap Oostendorp
John Todd

<http://naimit.eu>



1st Enpr EMA meeting 28th November 2011

Goal: European Paediatric Clinical Trial Network

Application: IMI1, IMI2, EFPIA

Translational approaches to disease modifying therapies in type 1 diabetes

10am to 4pm

Tuesday 29th July 2014

University Hospital Gasthuisberg,
Leuven, Belgium

**Chairs: Professor David Dunger
and Professor Chantal Mathieu**





[REDACTED]
Katholieke Univeriteit Leuven
Oude Markt 13
3000 Leuven
BELGIUM

[REDACTED]
IMI reference: IMI2/OUT/2015-01898

Brussels, 26 June 2015

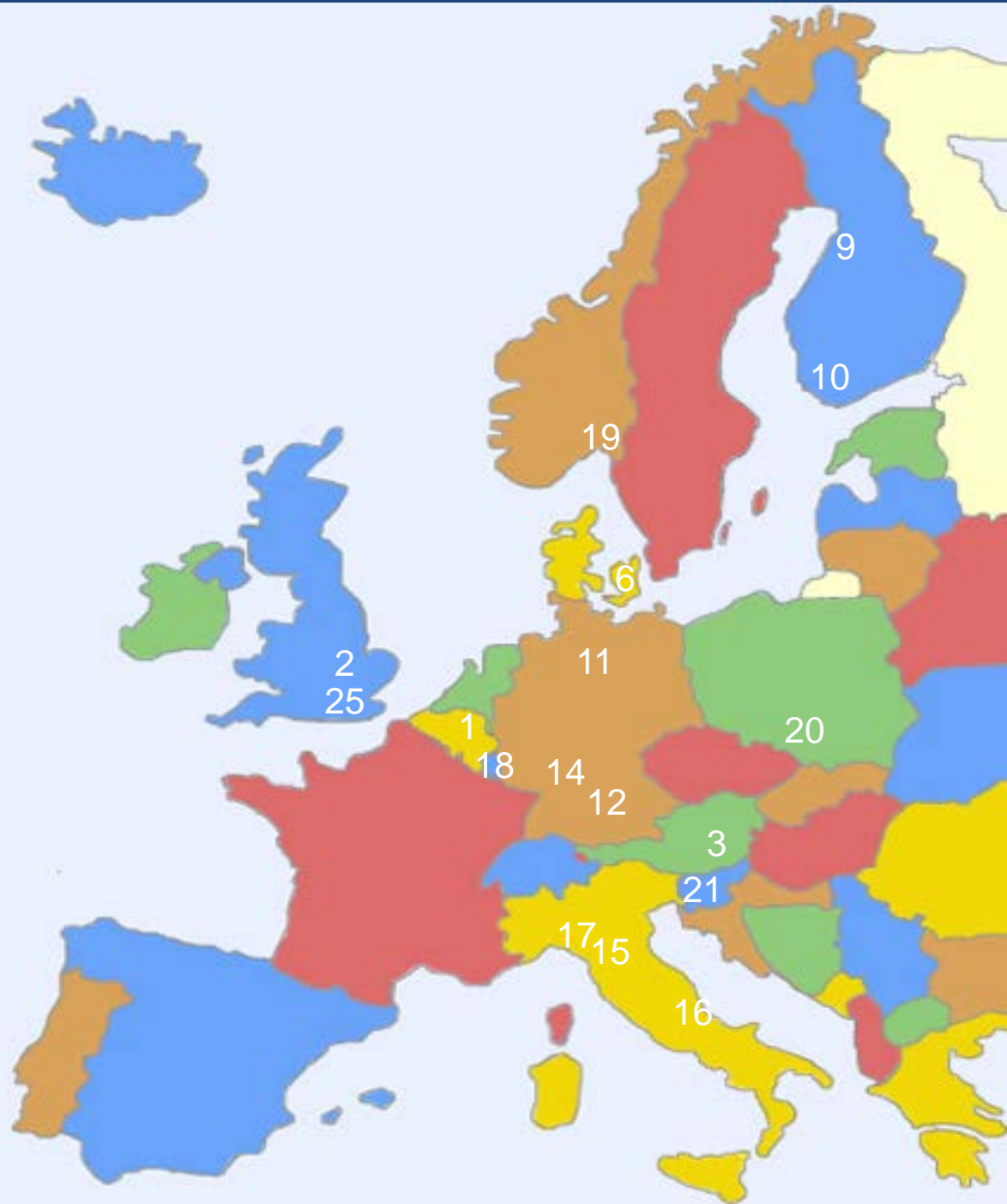
**Subject: Innovative Medicines Initiative 2 Joint Undertaking
Call for proposals: H2020-JTI-IMI2-2014-01
Proposal: 115797 – INNODIA
Result of Evaluation / Invitation to grant preparation**

Dear Coordinator,

We are pleased to inform you that the aforementioned proposal has been **favorably evaluated** by the Innovative Medicines Initiative 2 Joint Undertaking (IMI2 JU). Consequently, we wish to proceed to the preparation of the Grant Agreement based on your proposal.

Clinical Centres

Participant No	Acronym	Participants
1	KU Leuven	Casteels
2	UCAM	Acerini, Waldron-Lynch, Todd
3	MUG	Pieber
6	HH-RH	Mortensen
9	UOUL	Veijola
10	UTU	Lahesmaa
11	HKA	Danne
12	HMGU	Ziegler, Achenbach
14	UULM	Holl
15	UNISI	Dotta
16	UD'A	Chiarelli
17	UPI	Marchetti
18	CHL	De Beaufort
19	UIO	Dahl-Jørgensen
20	SUM	Jarosz-Chobot
21	ULI	Battelino
25	KCL	Tree
28	Sanofi	Ramos-Lopez
30	GSK	Napolitano-Rosen
31	Eli Lilly	Thomas
32	JDRF	Arnaud



efpia

European Federation of Pharmaceutical
Industries and Associations



SANDOZ

a Novartis company

Lilly



GlaxoSmithKline



novo nordisk®

Stakeholders

Independent Charities





JDRF



Helmsley

Chantal Mathieu, KUL, Leuven, Belgium
David Dunger, CIMR, Cambridge, UK

Knut Dahl-Jorgensen, UiO, Oslo
Geir Joner, UiO, Oslo
Torild Skriverhaug, UiO, Oslo

Mikael Knip, UH, Helsinki
Timo Otonkoski, UH, Helsinki
Riita Lahesmaa, UTU, Turku
Riita Veijola, UOUL, Oulu
Riita Lahesmaa, UTU, Turku

NovoNordisk

Decio Eizirik, ULB, Brussels
Miriam Cnop, ULB, Brussels
Pieter Gillard, KUL, Leuven
Kristina Casteels, KUL, Leuven

Soren Brunak, DTU, Lyngby
Flemming Pociot, UCPH, Copenhagen
Henrik Mortensen, UCPH, Copenhagen

John Todd, UCAM, Cambridge
Linda Wicker, UCAM, Cambridge
Frank Waldron-Lynch, UCAM, Cambridge
Chris Wallace, UCAM, Cambridge
Carlo Acerini, UCAM, Cambridge
Adrian Mander, MRC, Cambridge
Mark Peakman, KCL, London
Tim Tree, KCL, London

GSK

Bart Roep, LUMC, Leiden
Martin Gotthardt, RUMC, Nijmegen

Przemka Jarosz-Chobot, SUM, Katowice

Lilly

Anette Ziegler, HMGU, Neuherberg
Peter Achenbach, HMGU, Neuherberg
Ezio Bonifacio, TUD, Dresden
Michele Solimena, TUD, Dresden
Thomas Danne, HKA, Hannover
Reinhard Holl, UULM, Ulm

sanofi

Thomas Pieber, MEDUNI-GRAZ, Graz

Tadej Battelino, ULI, Ljubljana

Christian Boitard, INSERM, Paris
Roberto Mallone, INSERM, Paris
Rafael Scharfmann, INSERM, Paris
SARL Endocells (P Czernichow)

Bernard Thorens, UNIL, Lausanne, Switzerland

Francesco Dotta, UNISI, Siena
Piero Marchetti, UPI, Pisa
Francesco Chiarelli, UD'A, Chieti

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)

INNODIA

The logo for INNODIA features the word "INNODIA" in a bold, dark blue, sans-serif font. The letter "O" is replaced by a stylized, multi-faceted geometric shape composed of various shades of blue and a central red circle, resembling a molecular or crystalline structure.

General Assembly

1 representative per partner

Strategic Advisory
Board (SAB)

Ethical Advisory
Board (EAB)

Coordination Team

Coordinator (KU Leuven)
Project Leader (Sanofi)
Deputy Coordinator (UCAM)
Deputy Project Leader (JDRF)
Project Management team

Managing Board

Coordination Team + WP Leads

Representatives from Patient Advisory
Committee and Regulators

Project Management Team (WP6) (KU Leuven, Sanofi)

CSN-C

EUnPOD-C

WP 1

WP leadership
team

UCAM
Sanofi

WP 2

WP leadership
team

KCL
Novo

WP 3

WP leadership
team

ULB
Sanofi

WP 4

WP leadership
team

UCPH
HH-RH

CTN-C

WP 5

WP leadership
team

HKA
GSK

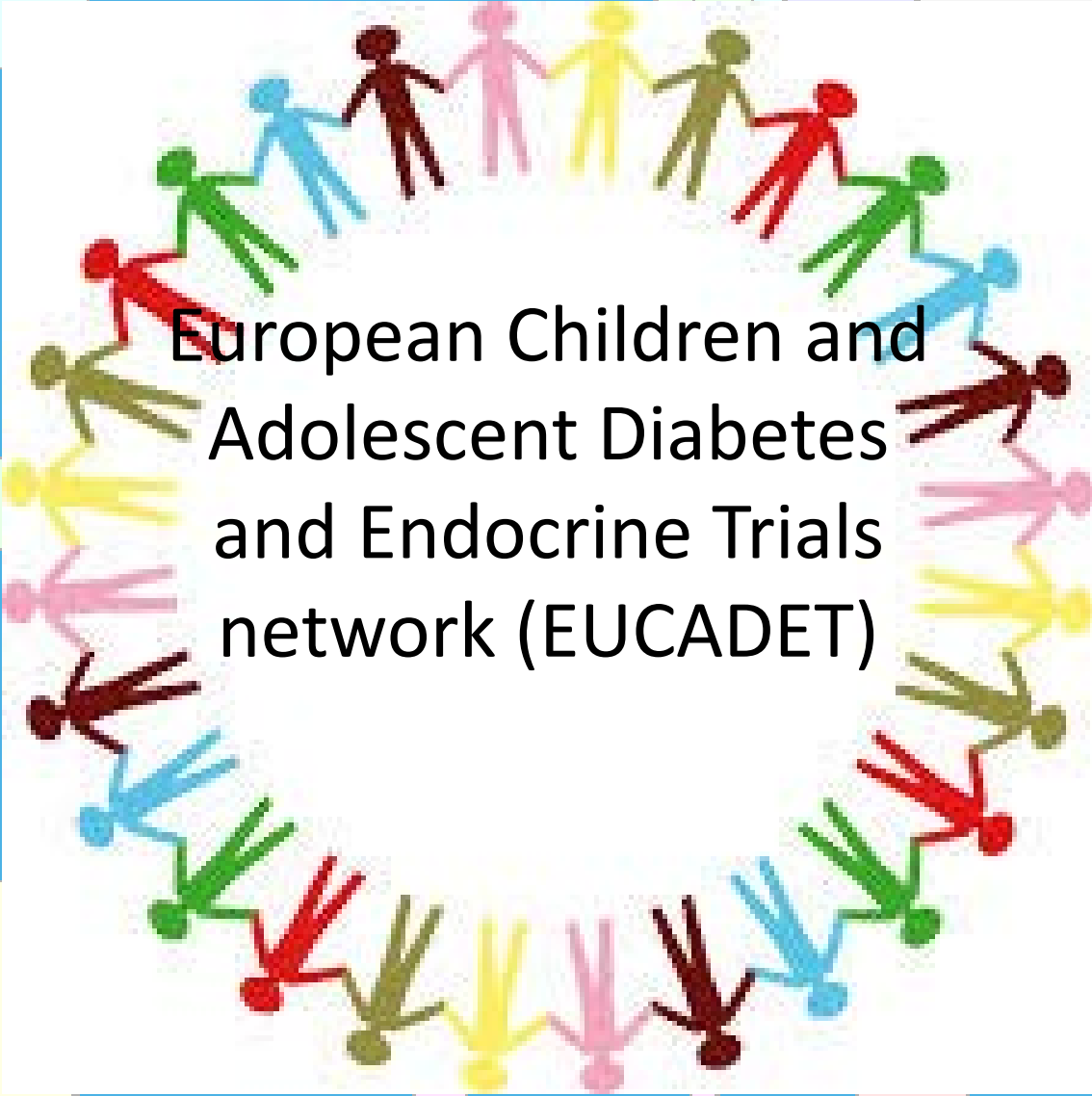
Patient Advisory Committee (PAC)

Going forwards in INNODIA

How do we engage with the EMA to accelerate the potential of INNODIA

To develop novel interventions , novel trial design , use of novel biomarkers which could accelerate and simplify drug development to prevent the progression of T1D in the newly diagnosed subject with T1D or reduce the risk of progression too T1D in those at risk in the normal population.

Could IMI-2 and INNODIA result in a novel relationship with EMA ,academia and industry which could accelerate and simplify drug development and provide an exemplar for other relatively rare paediatric endocrine disorders



European Children and
Adolescent Diabetes
and Endocrine Trials
network (EUCADET)