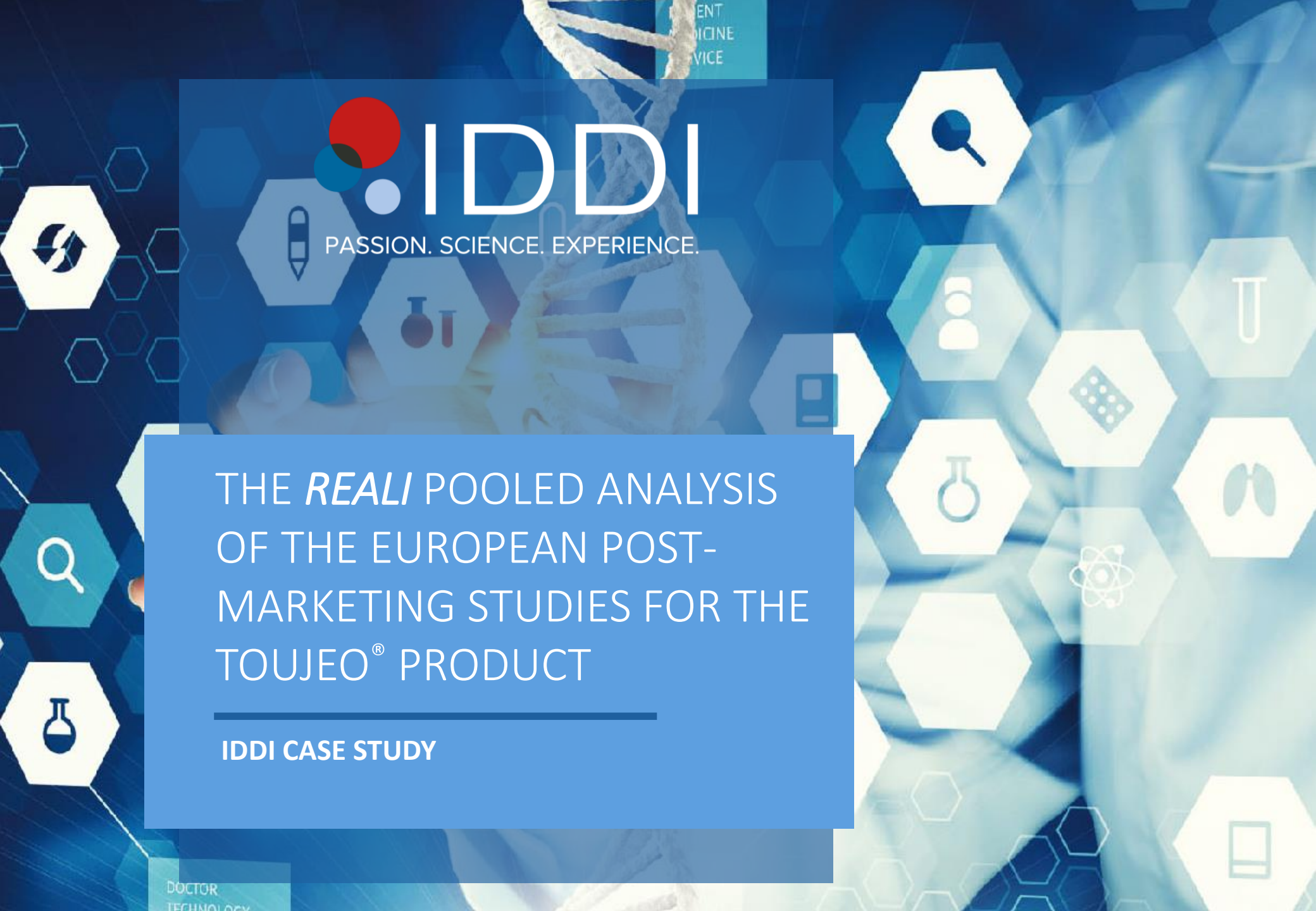


IDDI

PASSION. SCIENCE. EXPERIENCE.

THE *REALI* POOLED ANALYSIS OF THE EUROPEAN POST-MARKETING STUDIES FOR THE TOUJEO® PRODUCT

IDDI CASE STUDY

STUDY DESCRIPTION

The purpose of the *REALI* pooled analysis is to advance the understanding of the effectiveness and real world safety of insulin Gla-300 based on a large European patient database of postmarketing interventional and observational studies.

This study aims to identify and understand the variation in patients' experiences when treated with Gla-300, and to gauge selected patient characteristics that may be of interest to describe subsets of European populations with diabetes. To achieve these goals, the Sponsor uses two complementary statistical approaches, which enhance the chance of correctly identifying subgroups of patients with specific effectiveness and real-world safety patterns. Highlighting the profiles of patients who achieve greater glycaemic control will allow clinicians to provide personalized treatment plan to patients with diabetes.

INDICATION	PATIENT POPULATION	STUDY DURATION	REGIONS
Basal insulin in 1 or 2 doses			
Diabetes type I & II: T1DM (Type 1 Diabetes Mellitus) or T2DM (Type 2 Diabetes Mellitus)	10000 patients >= 18 year old patients with a confirmed diagnosis of T1DM or T2DM who initiated Gla-300 and were uncontrolled on their previous glucose-lowering treatments. The minimum treatment duration required is 24 weeks (6 months) of Gla-300 therapy.	Initial start date/ 01/07/2017 - end date: 05/01/2019	20 In Europe, Canada and Brazil

SITUATION

REAL-WORLD DATA FROM 16 DIFFERENT STUDIES IN DIFFERENT LANGUAGES

- Real-world data from over 10 000 patients with T1DM or T2DM.
- Pooled database that combines data from 16 studies run by the Sponsor's local divisions with the same requirements: Use of Toujeo®, minimum of 6-month treatment duration and collection of key endpoints such as HbA1c and hypoglycemic events
- The dataset used for the pooling is a mixture of data generated from both interventional and observational studies.

IDDI TASKS

- Statistical Analyses Plan
- SDTM Mapping for the pooling
- Statistical Programming
- Statistical Analyses

CHALLENGES

POOLING DATA FROM 16 COUNTRY-SPECIFIC STUDIES

DIFFERENT DATA COLLECTION STANDARDS

Substantial number of differences in the data collection standards due to the number of countries involved : different languages, different CRF's, different data collection methods, different types of data collected, different database structure and different coding dictionaries.

STATISTICAL CHALLENGES

Pooled efficacy and safety analyses of treated patients' data were performed on several subgroups of interests based on baseline characteristics from observational and interventional studies. A descriptive analysis was used to assess patient characteristics and clinical outcomes in the overall population and in patient subgroups.

COMPLEX PROCESS

De-identification of data by the Sponsor

↓

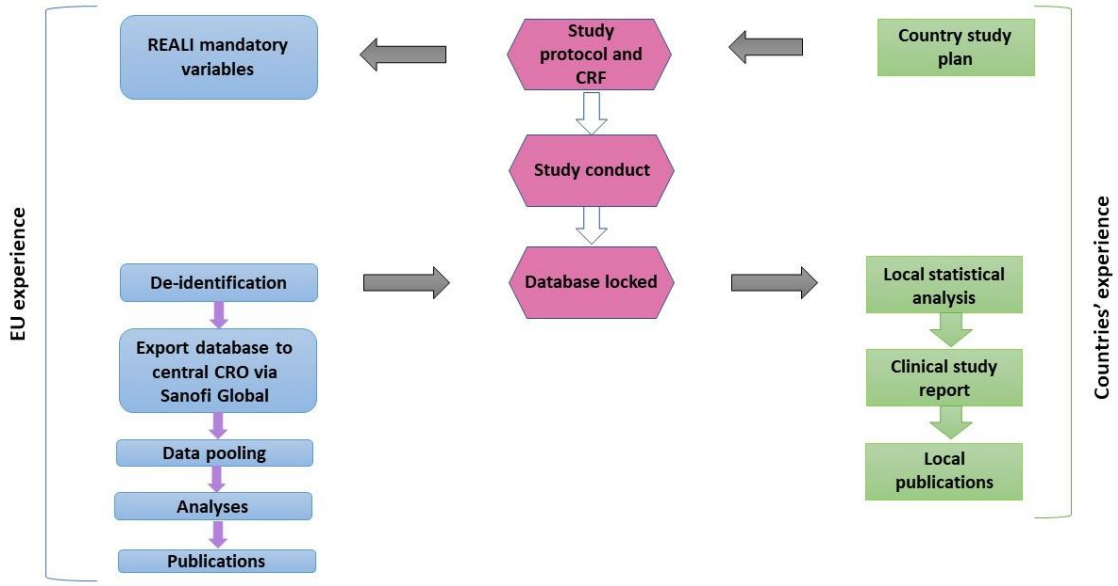
Database Harmonization at DM and STAT levels by IDDI

↓

Coding by the Sponsor

↓

SDTM Database – Statistical Analyses by IDDI

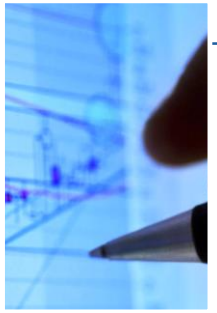


SOLUTIONS

IDDI's team extensive experience, flexibility and scientific background, combined with methodological and operational excellence, allowed to handle the complexity of this project.

IDDI produced **statistical reports** at overall and at subgroups level enabling the Sponsor to compare the results with the local CSR.

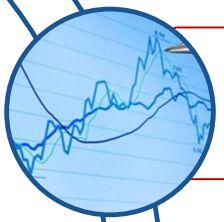
IDDI performed two sets of **programs, quality control and data homogenization** at Data Management and at Statistical level in order to identify missing data and work on equivalent variables



IDDI provided a substantial support in terms of **statistical data review** and data equivalence improving the quality of analysis.

RESULTS

ONE HOMOGENIZED SDTM DATABASE



POOLED ANALYSES OF OVERALL AND SUBGROUPS OUTPUT

→ **Help the Sponsor evaluate the impact of initiating insulin glargine 300 U/mL (Gla-300) in various subgroups, using the European pooled database.**

IDDI has successfully delivered

EXPERT STATISTICAL THINKING IN THE MEETINGS FOR THE DATA INTERPRETATION

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REVIEW AND SUPPORT FOR THE ABSTRACT AND POSTER SUBMISSION

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- **Abstract BMJ Open 2020;10:e033659. doi:10.1136/bmjopen-2019-033659**
- **Poster submitted at EASD 2019**
- **Second abstract in BMJ currently in process**

CONTACT US

For more information on IDDI's Trial Design - Randomization - Data Management and Biostatistics services for Pharmaceutical and Biotech companies:

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ABOUT IDDI

COMBINING PASSION, SCIENCE AND EXPERIENCE TO ENSURE YOUR CLINICAL DATA IS READY FOR SUBMISSION

International Drug Development Institute (IDDI) is an expert organization in biostatistical and integrated eClinical services that is committed to assisting pharmaceutical, biotech, medical devices, and Cooperative Groups in several disease areas, with a special focus on oncology and ophthalmology. IDDI optimises the clinical development of drugs, biologics and devices thanks to proven statistical expertise and operational excellence. Founded in 1991, IDDI has offices in Belgium, Boston (MA) and Raleigh (NC).