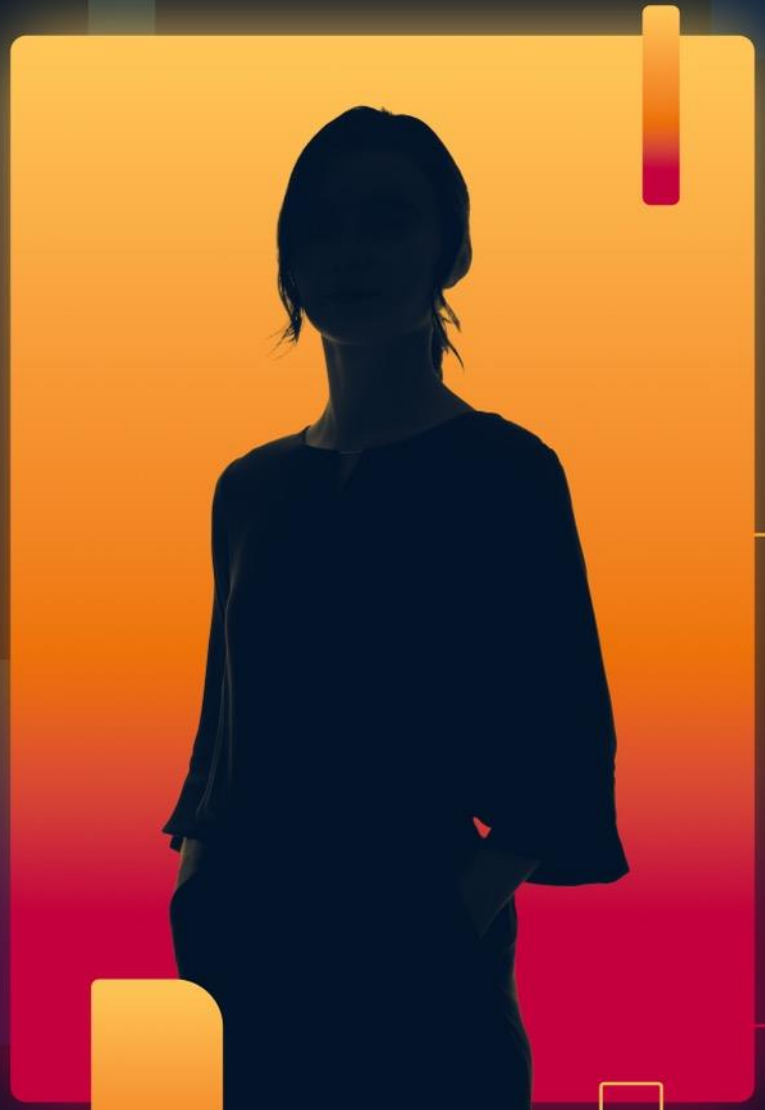


IDDI
DATA WITH PURPOSE

CASE STUDY

The *REALI* Pooled Analysis Of The European Post-Marketing Studies For The Toujeo® Product

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 post-marketing 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 glycemic control will allow clinicians to provide personalized treatment plans to patients with diabetes.

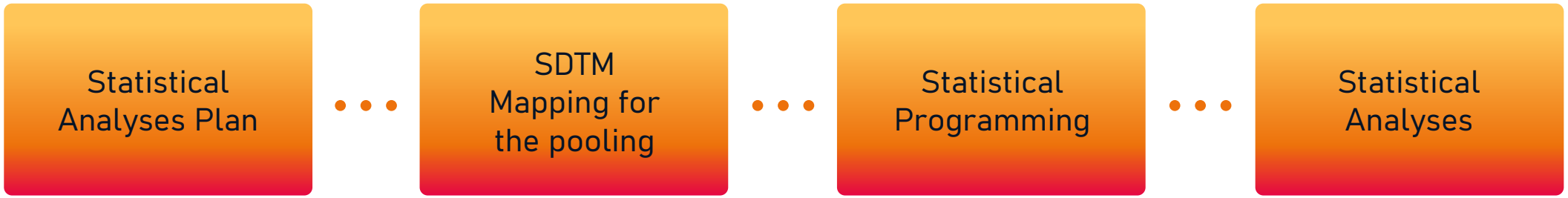
Indication	Patient population	Study duration	Regions
Basal insulin in 1 or 2 doses			
Diabetes type I & II: T1DM (Type 1 diabetes mellitus) or T2DM (Type 2 diabetes mellitus)	10,000 patients >= 18 year old patients with a confirmed diagnosis of T1DM or T2DM who initiated Gla-300 and were uncontrolled 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



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IDDI tasks

Statistical analyses plan • • • SDTM Mapping for the pooling • • • Statistical programming • • • Statistical analyses

Challenges (1)

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.

Challenges (2)

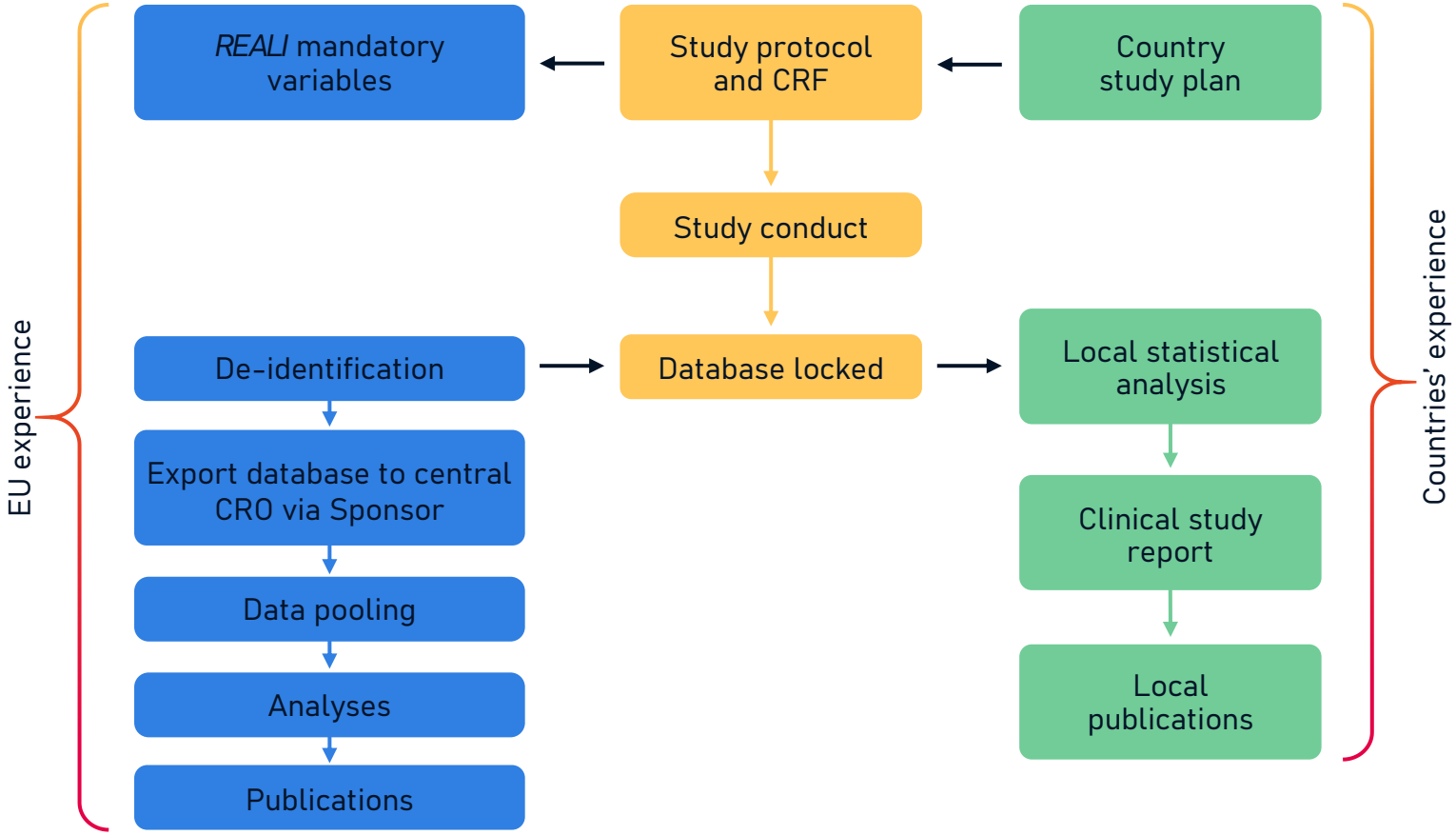
Complex process

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

Extensive experience, flexibility, and scientific background, combined with methodological and operational excellence, enabled IDDI to handle the complexity of this project.

Produced **statistical reports** at overall and at subgroup levels enabling the sponsor to compare the results with the local CSR.

Performed two sets of **programs, quality control, and data homogenization** at data management and at statistical level to identify missing data and work on equivalent variables

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

Results

IDDI has successfully delivered

- One homogenized **SDTM database**
- Pooled analyses of overall and subgroup output → Help the sponsor evaluate the impact of initiating insulin glargine 300 U/mL (Gla-300) in various subgroups, using the European pooled database.
- Expert statistical thinking in the meetings for the data interpretation
- Review and support for the BMJ abstract and poster submission →
  - 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

Whether you need assistance with your clinical strategy, study design, clinical data management, or biostatistical analysis, IDDI's experts are here to help.

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About IDDI

IDDI is a trusted clinical data science partner. With 35+ years of research-driven experience, we combine therapeutic expertise, biostatistical leadership, and regulatory insight to mitigate risk from design to registration and beyond.

We deliver uncompromising excellence in biostatistics, strategic consulting, clinical data management, IDMCs, and supporting eClinical technologies, because when every data point represents a patient, perfection is the only option.