



ENDOCRINE AND METABOLIC EXPERIENCE AND EXPERTISE

Challenge

Multicenter, Randomized, Open-label, 2-Arm, Parallel-group Study Comparing the Efficacy and Safety in Children and Adolescents with Type 1 Diabetes Mellitus with a Safety Extension Period

Optimapharm Approach

- Optimapharm carefully selected a well-known Principal Investigator
- Long-term experience with local institutions and sites; KOLs collaboration
- Knowledge of paediatric ICF and successful SIV

Outcomes

Achieved 160% of patient recruitment target (enrolled 20).

Completed 6 months early.

Audit and inspection of Ministry of Health with no significant findings.

Optimapharm Endocrine and Metabolic Overview

75

Endocrine - Metabolic clinical studies



Across **23** countries globally

300+

Sites involved

6%

Phase I studies

10%

Phase II studies

43%

Phase III studies

23%

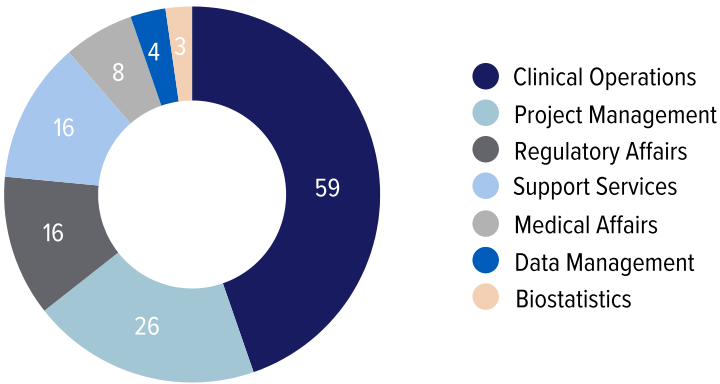
Phase IV studies



3470+ patients enrolled

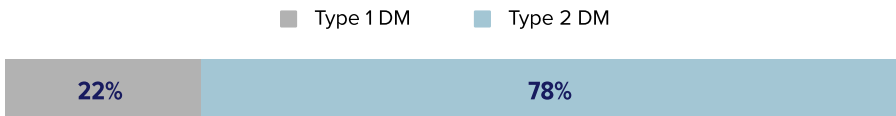


Optimapharm staff experience in Endocrine - Metabolic Studies



Experience in Diabetes Clinical Studies

Optimapharm has extensive experience in Diabetes studies, with 15+ studies conducted in the last five years. The chart below shows the distribution of Type 1 and Type 2 Diabetes studies.



Experience in Rare Endocrine - Metabolic Clinical Studies

Optimapharm has experience with rare endocrine - metabolic diseases in more than five indications. Some of our rare disease experiences: Lyosomal Acid Lipase Deficiency, Gaucher Disease, Niemann-Pick Type C, Fabry Disease, Transthyretin Amyloidosis, Mitochondrial Disease.

How Optimapharm can support your next study?

- Clinical Operations ● Project Management ● Medical Affairs
- Regulatory Affairs ● Safety & Pharmacovigilance ● Data Management & Biostatistics