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SCIENCE MEDICINES HEALTH

Objectives and Problem Statement

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Objectives

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- To identify elements for agreeing Paediatric Investigation Plans in T2DM in line with good clinical practice and delivering conclusive outcomes.

- To identify approaches to enhance feasibility of paediatric T2DM trials.

Problem Statement

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- The European Paediatric Regulation: Agreement on paediatric development via so called paediatric investigation plans (PIP) before filing adult marketing authorization application, unless a waiver is granted.

- Motivation for developing novel T2DM drugs is revenue expected from the adult market (high adult T2DM prevalence).

- Still limited paediatric T2DM patient population.

Type 2 Diabetes Mellitus PIPs

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Products for the treatment of type 2 diabetes mellitus, with an agreed Paediatric Investigation Plan (2007 - present)		
Product	**Mechanism of action**	**Authorised in the EU**
Saxagliptin	DPP4 inhibitor	Yes (Onglyza)
Linagliptin	DPP4 inhibitor	Yes (Trajenta)
Alogliptin	DPP4 inhibitor	No
Sitagliptin	DPP4 inhibitor	Yes (Januvia and other names)
Omarigliptin	DPP4 inhibitor	No
Liraglutide	GLP1 analogue	Yes (Victoza)
Albiglutide	GLP1 analogue	No
Taspoglutide	GLP1 analogue	No
GLP-1 analogue linked to human IgG4 Fc-fragment	GLP1 analogue	No
Lixisenatide	GLP1 analogue	No
Exenatide	GLP1 analogue	Yes (Byetta, Bydureon)
Canagliflozin	Sodium glucose co-transporter 2 inhibitor	No
Dapagliflozin	Sodium glucose co-transporter 2 inhibitor	Yes (Forxiga)
BI 10773	Sodium glucose co-transporter 2 inhibitor	No
TAK-875	G-protein coupled receptor 40 agonist	No
Bromocriptine (mesylate)	Dopamine agonist	No