Methods, quality control and specimen management in an international multicentre investigation of type 1 diabetes: TEDDY.

The vast array and quantity of longitudinal samples collected in The Environmental Determinants of Diabetes in the Young study present a series of challenges in terms of quality control procedures and data validity. To address this, pilot studies have been conducted to standardize and enhance both biospecimen collection and sample obtainment in terms of autoantibody collection, stool sample preservation, RNA, biomarker stability, metabolic biomarkers and T-cell viability. The Environmental Determinants of Diabetes in the Young is a multicentre, international prospective study (n = 8677) designed to identify environmental triggers of type 1 diabetes (T1D) in genetically at-risk children from ages 3 months until 15 years. The study is conducted through six primary clinical centres located in four countries. As of May 2012, over three million biological samples and 250 million total data points have been collected, which will be analysed to assess autoimmunity status, presence of inflammatory biomarkers, genetic factors, exposure to infectious agents, dietary biomarkers and other potentially important environmental exposures in
relation to autoimmunity and progression to T1D. Detailed procedures were utilized to standardize both data harmonization and management when handling a large quantity of longitudinal samples obtained from multiple locations. In addition, a description of the available specimens is provided that serve as an invaluable repository for the elucidation of determinants in T1D focusing on autoantibody concordance and harmonization, transglutaminase autoantibody, inflammatory biomarkers (T-cells), genetic proficiency testing, RNA lab internal quality control testing, infectious agents (monitoring cross-contamination, virus preservation and nasal swab collection validity) and HbA1c testing.

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