

International Severe Asthma Registry: A Real-life Data Capture Model

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Rationale: (53 words)

Registries are valuable resources to study the natural history of diseases, diagnostic accuracy and effectiveness of therapies. Currently, severe asthma registries comprise of relatively small, locally administered databases with little interoperability. We describe the creation of a real-life data collection model for International Severe Asthma Registry (ISAR), the first global severe asthma registry.

Methods: (121 words)

ISAR collects data from pre-existing registries, and also supports the establishment of new local registries. For existing local registries, standardized data fields are adopted into pre-existing electronic data capture systems (EDC). Data field selection process for ISAR was determined using a Delphi exercise. For new registries, electronic case report forms of the standardized data fields are provided via EDC with flexible study design, such as REDCap and OpenClinica. Patient-reported outcomes (PROs) forms are delivered to patients prior to visits and incorporated into the registry to maximize data capture.

Data is hosted in a secure, password-protected central registry per GDPR policy. Data quality is ensured from the point-of-entry to analysis, with validation rules automatically detecting and logging anomalous data entry for review.

Results: (52 words)

As of August 2018, seven countries have participated in ISAR (USA, Greece, Ireland, South Korea, UK, Australia and Italy), comprising of 4 pre-existing and 3 new registries, contributing standardized data from >3,000 patients. An additional 15 countries are currently planned to participate. Data collected include bio-markers, lung function, diagnostics, PRO and medication.

Conclusions: (22 words)

ISAR captures a large volume of standardised data from multiple countries, providing a basis to answer important research questions in severe asthma.