G. Walter Canonica, 1

1 Snapshot Agreements In Progress

the ISAR gain a better understanding of the natural history of their disease (collective data being used to inform (current planned) gain deeper insights to facilitate and promote education and training on severe asthma

1 Describe the first international adult severe asthma registry (ISAR)

2 A list ISAR core projects and prioritized research initiatives are summarized in

696 The individual data is prospective for 1,295 patients and retrospective for 5,137 patients. 2019 Asthma severity, patient details, occupation, medical history (e.g. exacerbations, and healthcare resource utilization variab

43:343 The full list of core variables has already been published.

5 A collaboration agreement with each country covered method of and provided consent for their prospective data to be included.

Scientists Patients

Pooling resources to generate a centralized severe asthma dataset

Bulathsinhala 5

The International 2019 Patients in ISAR are aged ≥18 years old, received treatment at Global Initiative for Asthma (GINA) Step 5, or had uncontrolled asthma (i.e. severe symptoms or frequent exacerbations) at GINA Step 4 (at inclusion), and provided consent for their prospective data to be included.

With such a large dataset:

May 81 15 563

Combining registries from different countries ensures data capture on a broader range of severe asthma patients, intra... evidence on how treatments are used and their effectiveness in different patient populations; and

ICU/ICD case, observational real-time study.

• It is a joint initiative where national registries (both newly created and pre-existing) retain ownership of their data, but open their borders and share data with ISAR for ethically approved research purposes.

• ISAR’s strength comes from collection of patient level, anonymous, longitudinal, real-life, standardized (using a core set of variables), and high-quality data from countries across the world, combined with organized structure, database experience, inclusivity/openness, and clinical, academic, and database expertise (Figure 1).

• Data collection is supported by the use of a dedicated template and integration with existing electronic data capture (EDC) systems (e.g. OpenClinica). These EDC systems ensure data quality via data validation and editing at the point of data entry.

• A collaboration agreement with each country covered method of transmission and storage of data, data security, compliance with data security standards, data protection and privacy, and list of core variables required for extraction from each local registry. Data is transferred quarterly for most countries.

• The aim of this poster was to:
  o Describe the first international adult severe asthma registry (ISAR)
  o Summarize what ISAR brings to the field of severe asthma
  o Provide a snapshot of data already captured

Methods

Patients included

• Patients in ISAR are aged ≥21 years old, received treatment at Global Initiative for Asthma (GINA) Step 5, or had uncontrolled asthma (i.e. severe symptoms or frequent exacerbations) at GINA Step 4 (at inclusion), and provided consent for their prospective data to be included.

Variables included in ISAR

• ISAR initially captured 95 core variables which have been agreed by Delphi consensus, and classified into 13 categories:
  o Asthma severity, patient details, occupation, medical history (e.g. exacerbations, and healthcare resource utilization variables), co-morbidity, blood/sputum, diagnostic, lung function, allergen testing, asthma control, asthma medication, adherence, and management plan.
  o The full list of core variables has already been published.2
  o Additional variables have now been added to capture information on severe infection, malignancies, anaphylaxis, additional co-morbidities, time of exacerbation, ICS/ICS dose, and reason(s) for medication switching.

Results

• ISAR already partners with 19 national or regional registries in Europe (Bulgaria, Denmark, Greece, Ireland, Italy, Netherlands, Spain, UK), The Americas (USA, Canada, Columbia, Mexico), Asia Pacific (Japan, India, South Korea, Taiwan) and the SAWD registry comprising patient data from Australia, New Zealand, and Singapore), and the Middle East (Kuwait, UAE), with planned expansion to other regions of the world.

• Agreements are in process with, Finland, Germany, Iceland, Norway, Sweden, Argentina, Singapore and Saudi Arabia, with many more countries

• ISAR currently comprises data from 7,826 severe asthma patients (individual data: n=6432; aggregate data: n=1394) and continues to grow (Table 1).

• The individual data is prospective for 1,295 patients and retrospective for 5,137 patients.

• ISAR aims to collect prospective data on at least 13,150 patients worldwide.

• New data are provided regularly, improving generalizability to the wider severe asthma population.

• The size of ISAR means that we have, for the first time, a dataset large enough to discern small clinically significant differences and rare outcomes which, until now, has been beyond our grasp and to allow a better understanding of regional differences.

• A list ISAR core projects and prioritized research initiatives are summarized in Table 2.

What is ISAR?

• The International Severe Asthma Registry (ISAR); http://isardregistry.org/ is the first global adult severe asthma registry: a multi-country, multi-center, observational real-life study.

• It is a joint initiative where national registries (both newly created and pre-existing) retain ownership of their data, but open their borders and share data with ISAR for ethically approved research purposes.

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Table 1. ISAR Snapshot: May 2019

<table>
<thead>
<tr>
<th>Country/Registry</th>
<th>Site</th>
<th>Patient data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bulgaria</td>
<td>10</td>
<td>131</td>
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<tr>
<td>Canada</td>
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<td>81</td>
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<tr>
<td>Greece</td>
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<td>28</td>
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<td>Ireland</td>
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<tr>
<td>Total</td>
<td>124</td>
<td>7,200</td>
</tr>
</tbody>
</table>

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GLOBAL CORE PROJECTS

Demographic and clinical baseline characteristics of severe asthma patients worldwide

The characterization and comparison of eosinophilic and non-eosinophilic phenotypes

Determining effectiveness across severe asthma biologic classes (Anti-IL-5 vs. Anti-IL-5) in patients eligible for both indications

PRIORITY RESEARCH

Hidden severe asthma patients in primary care

The role of asthma exacerbations on lung function trajectory

Bioligics in severe asthma: Utilization patterns, causes for discontinuation and switching, and adverse outcomes

Assessment of the overlap (relatability) of collected biomarkers

Identification of predictors (i.e. biomarkers) of response to biologics

Hidden chronic asthma within the COPD/ACOS population

Age at onset of asthma in severe asthma patients

Relationship between socio-economic status & asthma outcomes

Describe the OCS landscape: annual consumption, prevalence, outcomes and side-effects of long-term OCS users

Outcomes of switching between Anti-IL-5 receptor a chain monoclonal antibody and Anti-IL-5 monoclonal antibody therapy in severe asthma

Characterization of health disparities (burden of illness or mortality) across countries

Criteria for choosing and switching between similar biological treatment options in patients with atopic and non-atopic severe eosinophilic asthma

Results

• Combining registries from different countries ensures data capture on a broader range of severe asthma patients, intra-operability between registries, and facilitates robust assessment of the impact of therapeutic interventions.

• Such a large dataset, comprising high quality, standardized and individual level patient data, provides a fertile ground for clinically-relevant scientific study and the potential to publish key findings in international peer-reviewed Journals.

• With such a large dataset:
  o Clinicians gain information on patient presentation and predictors of treatment success;
  o Scientists have the opportunity to use the information gathered for ethically approved academic research;
  o Educators gain deeper insights to facilitate and promote education and training on severe asthma
  o Patients gain a better understanding of the natural history of their disease (collective data being used to inform treatment guidelines);
  o Payers get evidence on how treatments are used and their effectiveness in different patient populations; and
  o The pharmaceutical industry can assess the real burden of disease and the effectiveness and long-term safety of therapeutic agents in real-life.

References


Acknowledgements

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