Real life treatment patterns and outcomes in advanced Melanoma patients in Italy and Sweden: The development of a Multi Country Database

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Introduction

The field of healthcare in general is experiencing a major paradigm shift as new ways of dealing with life-threatening diseases become available. Nowhere is this more evident than in the field of melanoma, where the recent development in immuno-therapy and targeted therapies is providing new treatment options that from one side are radically changing the natural history of this disease, with really improved clinical outcomes, but on the other, they question the sustainability of health systems in consideration of their high costs. Assessing the broad applicability of these emerging options, calls for clinical trials to be complemented by inter-country, population based real-world evidence.

Aim

To create an international data platform on malignant melanoma treatment that can be used to create large real-world databases that sustain clinical and epidemiological studies designed to systematically observe and describe patient treatment processes and outcomes.

Rationale

The pace of pharmaceutical research in the area of malignant melanoma and other cancers is growing rapidly and presenting new treatment alternatives that call for evidence-based guidance. Since 2011 four immunotherapeutic drugs and four targeted therapies have been approved by the FDA. Although these treatments have gone through clinical trials, assessing how their wider take-up can and should be proposed, calls for observational studies based on patient data sets that are sufficiently robust to sustain population based analysis. To date, this has not been possible because of many of the data sets generated by clinicians and clinics were small and not shared. In order to help overcome these shortcomings, the MCD platform project here seeks to develop large real-world datasets that can be used to assess treatment outcome patterns.

Methods

A core research team involving two independent groups in Denmark and Switzerland developed a Research Concept Model (RCM) to guide potential clinical researchers and institutions, and set the scene for research management. The RCM has in turn also become the basis for an Inter-Country Protocol (ICP) and a Research Governance Framework (RGF) that ensures common research operation principles and values, as well as a standardized methodology for researchers and other stakeholders, including donors.

The RGF highlights the need for all national ethical requirements, including patient data approval, to be met and respected. It stresses management of data by a third party Academic Research Organization (ARO), in collaboration with the Steering Committee, ownership of national data by participating centers, linkage of data where research questions have been submitted, reviewed and approved as per the RGF. It also stresses that individual patient data will only be available to the clinical centers that are responsible for those patients.

The ICP provides the methodology for drawing on clinical datasets of patients diagnosed with stage III and IV melanoma that were not necessarily created as a basis for generating comparative research data.

Within a defined study time window, patients data are included in the MCD if the index date for a specific event falls in the window. Patient information refer to the healthcare pathways at the single center participating in the MCD project, and they contain patients characteristics, medical history with previous treatment, and all the available data on patient health care management, included health care resources utilization.

It outlines several levels of collaboration, including data extraction and data transfer, centralized data analysis at the MCD platform level, and access to MCD data for special sub-studies proposed by collaborating research teams. At the MCD level, for example, it outlines how and why different levels of analysis are proposed and how these will be used in providing results.

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