# 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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Figure 1. MCD Project: Outline of target database (= analysis database)
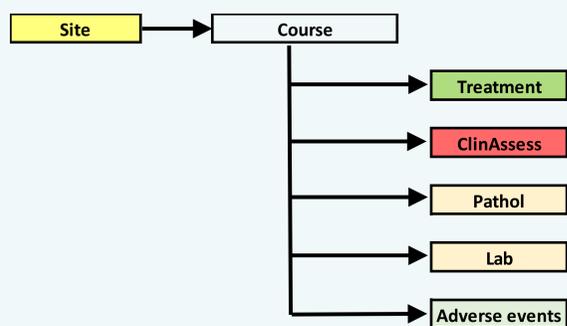
Results

A Pilot Study in Italy (IRST) and Sweden (Karolinska Institute) covered the regions Romagna and Stockholm, representing a total population of approximately 3.4 million people. Data from the clinical referral centers have been centralized and this has demonstrated that observational data drawn from primary data sources that were not necessarily designed to generate analytic treatment data can be successfully shared and used to provide a real-world image of treatment and treatment options. Key information on patient demographics, date of diagnosis and start of treatment, type of treatments involved, disease progression, and treatment outcomes have been standardized and compiled in the Multi Country Database (MCD) platform with a focus on patient courses and not just on treatments.

Conclusions

There is good reason to believe that the Multi Country Database methodology developed as part of this project will go on to encourage more data sharing, and will provide a new forum for research on melanoma and other disease treatment processes and outcomes. The study has nevertheless highlighted the importance of harmonizing data collection, and data transfer procedures and the time that can be taken up doing this if and where different primary data collection methods are not uniform.

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.
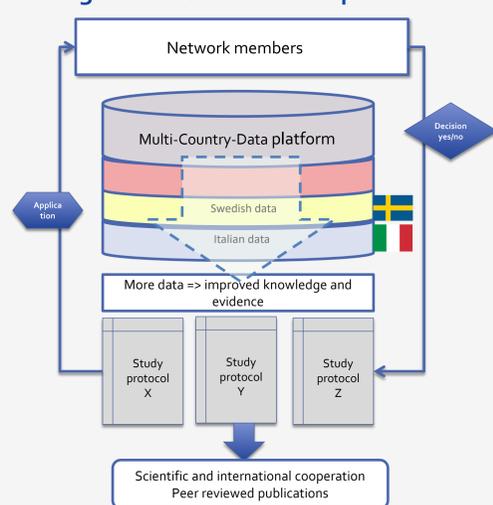
Rationale

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 reported 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.

Figure 2. Research Concept Model

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.
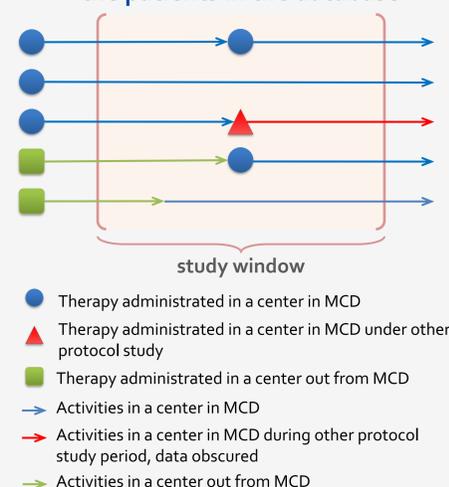
Figure 3. Governance Structure

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.

Figure 4. Pattern of inclusion of the patients in the database

study window

- ● Therapy administrated in a center in MCD
- ▲ Therapy administrated in a center in MCD under other protocol study
- ■ Therapy administrated in a center out from MCD
- → Activities in a center in MCD
- → Activities in a center in MCD during other protocol study period, data obscured
- → Activities in a center out from MCD

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