**BACKGROUND**

EUnetHTA Joint Action 2 (J2A) is currently evaluating the applicability of the Core Model® for Rapid Relative Effectiveness Assessment of Pharmaceuticals (WPS) of selected drugs for which a market authorization is intended between 2013 and 2015. This pilot is a methodological framework that enables the production of high quality HTA information in a structured format to support the production of local (national or regional) HTAs and reuse of existing information. Another goal is to develop and test a methodological basis for European cooperation on HTA guidelines for distinct methodological issues and quality improvement of evidence generation for HTA [1].

A global value dossier (GVD) represents an important tool for pharmaceutical manufacturer (PM) to consolidate information on considered disease, its management and treatment, epidemiology, as well as health economic outcomes. The current study intended to quantify the information that is transferrable from a well prepared, comprehensive GVD to EUnetHTA submission via gap analysis.

The EUnetHTA J2A WPS dossier comprises of 4 modules: 1. Description of the health problem; 2. Technical characteristics of technology and appropriate comparator(s); 3. Clinical effectiveness; and 4. Safety of the new drug.

**METHODS**

- First, a gap analysis was performed to quantify the amount of missing information that could not be informed from an existing GVD.
- Then, potential measures to close the remaining gaps in the EUnetHTA dossier were evaluated and the optimal approach was carried out, such as identification of other drug specific sources of information and additional literature searches.
- Finally, EUnetHTA dossier was completed. For this analysis the type of additional sources required and their relative contribution were assessed for the overall dossier and per module.

**RESULTS**

**Main findings:**

- Only 15.8% of the dossier could be completed with the information available from the GVD (Graph 1).
- Most of the information required was retrieved from PM (internal documents, answers to authorities and clinical experts – 35.4%) and the Clinical Study Report (CSR – 22.7%) (Graph 1).
- Nevertheless, 12.4% of the EUnetHTA dossier remained as Gaps, for which additional research would be needed (Graph 1).
- The type of source used to complete the dossier differed for each of the four modules (Graph 2a–d).

**The most challenging gaps:**

- Epidemiology data for all European countries: a thorough literature search should be carried out to obtain the data necessary.
- Management of the disease: a systematic search of guidelines, literature and registries should be completed.
- Clinical data: specific calculation and analysis need to be done for HTA purposes.
- Use of the technology: the potential harms should be described after search of official reports on drug safety.

**CONCLUSIONS**

1. A GVD can be a useful pool of knowledge for a new drug in a specific indication. However, a considerable part of information, which is required for a EUnetHTA submission will be missing even in far-reaching GVDs.
2. Additional information required may be derived from existing clinical study reports, extensive systematic literature searches, internal sources and additional evaluations (epidemiological and quality of life studies, clinical data analysis).
3. Applying of validated and systematic methods during the GVD development process may reduce additional work for assessment reports.