

# The Relevance of Real World Evidence Studies in the German Benefit Assessment (AMNOG) Process

Kathrin Borchert, Jan-Frederik Löpmeier, Sebastian Braun, Christian Jacob  
Xcenda GmbH, Hannover, Germany

## BACKGROUND

- In 2011, a new Health Technology Assessment (HTA) concept with the Act on the Reform of the Market for Medicinal Products (AMNOG) regulation was introduced in Germany.
- All submitted German benefit assessments for pharmaceuticals are publicly available on the website of the Federal Joint Committee (G-BA).<sup>1</sup>
- The AMNOG obliges pharmaceutical companies to submit a benefit dossier to the G-BA at market launch, estimating epidemiological data of the underlying disease, data on morbidity and mortality, health-related quality of life, and annual therapy costs and providing granular data on medical benefits compared to the appropriate comparative therapy.

## OBJECTIVES

- Aim of this study was to investigate the integration of Real World Evidence (RWE) data in German AMNOG dossiers to determine the incidence and prevalence of the underlying disease and the quantification of target populations.
- Furthermore, the study aimed at investigating the relevance of different data sources over time since the introduction of AMNOG in 2011.

## METHODS

- All benefit assessments with published AMNOG dossiers between 01 January 2011 until 31 December 2018 were included in the analysis.
- For this purpose, all available Modules 3 of each active substance were downloaded from the website of the G-BA.
- Relevant sections of the respective Modules 3 were screened for the integration of RWE data in terms of Statutory Health Insurance (SHI) claims data, registry data, surveys, and/or other data sources (e.g. chart reviews, outpatient practices data, pharmacy billing centers, patient medical records) to assess epidemiological measures.
- The respective chapters 3.2 were searched for the following terms with the program Docfetcher: \*Datenquelle\* (data source), \*Datenpool\* (data pool), \*Krankenkasse\* (health insurance), \*Kassendaten\* (insurance data), \*Datenanalyse\* (data analysis), \*Datenauswertung\* (data evaluation), \*Abrechnungsdaten\* (claims data), \*Routinedaten\* (routinely collected data), \*Sekundärdaten\* (secondary data), \*Versichertendaten\* (data of insured persons), \*Register\* (registry), \*Befragung\* (interview), \*Panel\* (panel), \*Survey\* (survey).
- Additionally, a hand search was conducted based on the names of the previously identified study vendors/authors and the applied methods (38 search terms).
- The identified matches were verified by two independent reviewers by full text search inspecting the chapters with matches and additionally the respective chapters 3.2.5 / 3.2.6 „Informationsbeschaffung“ (information acquisition).
- For the analysis of relevance over time, the obtained data were analyzed for the years 2011 to 2018. In the case of multiple submissions for pharmaceutical products, the year with the first submission of RWE data was used.
- In addition, trends over time from 2011 to 2018 were explored for each data source category.

## RESULTS

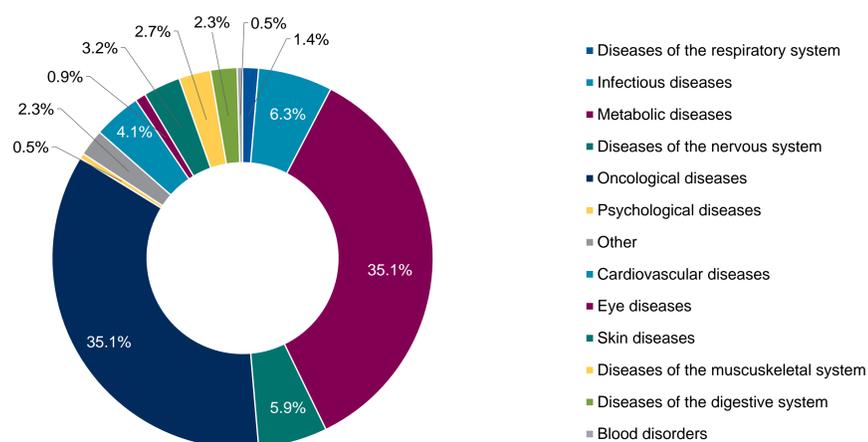
### Use of RWE Studies

- In total, N=456 different target populations (Modules 3) could be extracted for the years 2011 to 2018 from the website of the G-BA.
- This corresponds to N=227 different active compounds in N=356 AMNOG dossiers.
- After reviewing the matches found with the defined search terms via Docfetcher in the respective Modules 3 and full text search, n=222 (48.7%) of N=456 Modules 3 incorporating RWE studies exploring overall patient counts in the underlying diseases and the target populations were identified.
- With regard to active compounds, n=115 out of the total N=227 assessed pharmaceuticals (50.7%) used RWE studies.

### Indication Areas With RWE Data

- The most common indication areas integrating RWE in Modules 3 included oncological diseases and metabolic disorders (both 35.1%), followed by infectious diseases (6.3%), and diseases of the nervous system (5.9%) (see Figure 1).

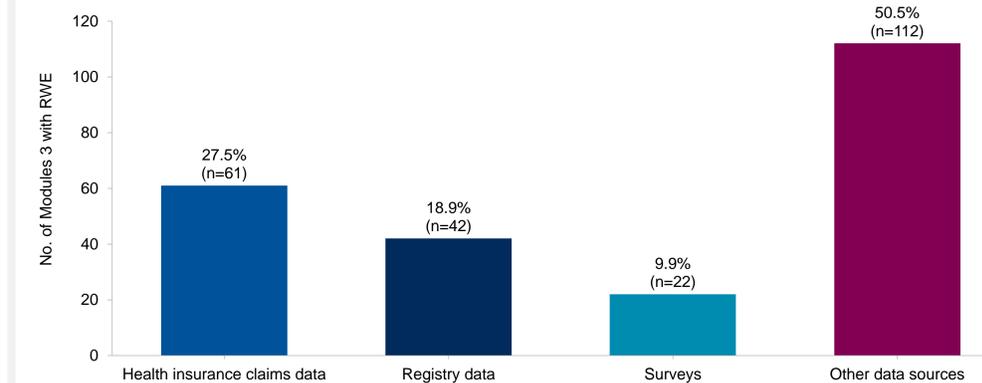
Figure 1. Indication Areas With RWE Data (N=222)



## RWE Data Sources

- Out of all identified Modules 3 incorporating RWE data (N=222), the following types of RWE data were identified: n=112 (50.5%) employed studies with other data sources (such as chart reviews, outpatient practices data, etc.) and in n=61 (27.5%) SHI claims data were used.
- Registry data were employed in n=42 (18.9%) and surveys were performed for n=22 (9.9%) (see Figure 2).

Figure 2. RWE Data Sources (N=222)

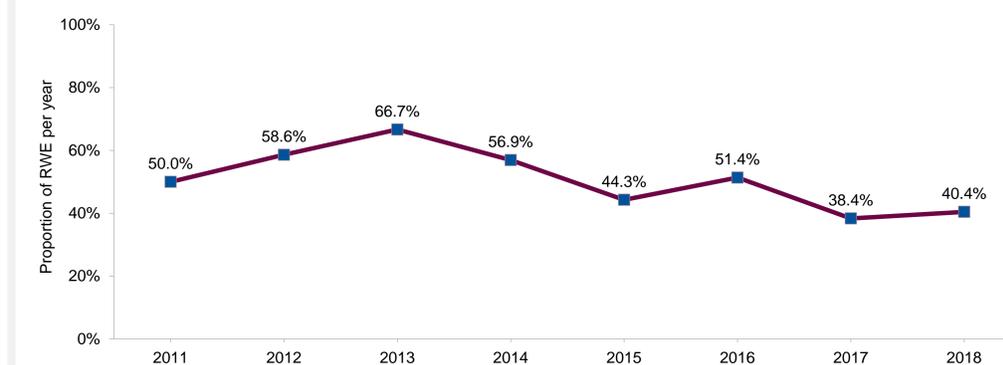


Note: Numbers do not sum up to N=222 as more than one RWE data source is possible.

## Relevance of RWE Over the Course of Time

- Between 2011 and 2018, the incorporation of RWE studies varied from 38.4% in 2017 to 66.7% in 2013. An increase of RWE studies until 2014 was observable, with a strong decline in 2015 and fluctuations until 2018 (see Figure 3).

Figure 3. Trend of RWE Between 2011 and 2018

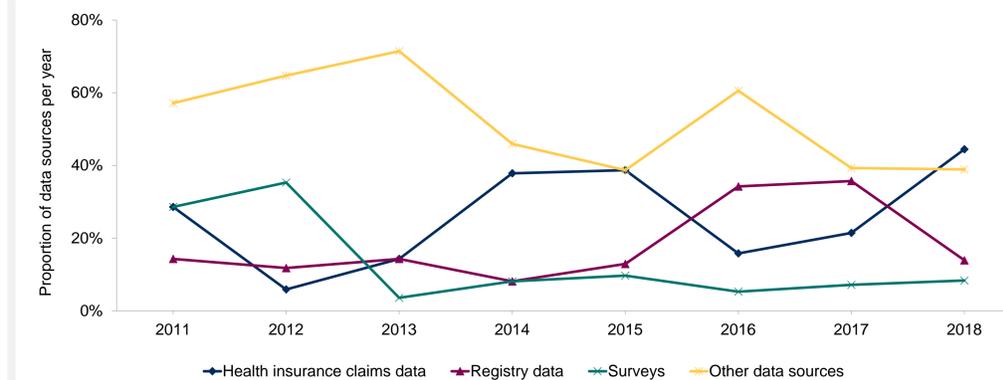


Note: Percentages are based on the number of RWE studies and the corresponding total number of Modules 3 in each year.

## Relevance of RWE Data Sources Over the Course of Time

- Stratifying by RWE data type, a decreasing trend in the application of registry data and surveys was observable until 2018, whereas other data sources and claims data showed a strong increase until 2013/2014 and again in 2016/2018 (see Figure 4).

Figure 4. Trend of RWE Data Sources Between 2011 and 2018



Note: Percentages are based on the number of studies with the respective RWE data source and the corresponding total number of Modules 3 in each year.

## CONCLUSIONS

- This study revealed that the integration of RWE data has almost become a standard component in German AMNOG dossiers since its introduction in 2011.
- The application of RWE data in German AMNOG dossiers has demonstrated a high relevance in the first years of the benefit assessments.
- German SHI claims data constitute, besides registry data and other data sources, a valid and reliable data source for the determination of epidemiological evidence.
- Indication-specific claims data analyses are a meaningful and more current contribution to existing literature and can supply comprehensive information such as demographics, outpatient and inpatient care, prescriptions, devices and aids, incapacity to work, and sick leave payments.

## REFERENCES

- Gemeinsamer Bundesausschuss (G-BA). Nutzenbewertung von Arzneimitteln gemäß § 35a SGB V. 2019. <https://www.g-ba.de/institution/themenschwerpunkte/arzneimittel/nutzenbewertung35a>. Accessed 15 October 2019.