# 10 Years of AMNOG: Importance of Real World Evidence Studies in the German Benefit Assessment Process

HTA92

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## BACKGROUND

- A new Health Technology Assessment (HTA) concept was introduced in Germany with the Act on the Reform of the Market for Medicinal Products (AMNOG) in 2011.
- At market launch, the AMNOG obliges pharmaceutical companies to submit a value dossier to the Federal Joint Committee (G-BA), which contains five modules (Module 1-5).
- Module 3 requires inter alia epidemiological data of the underlying disease, a trend analysis for the prevalence and incidence in the upcoming five years, and an estimation of the target population.
- Since its introduction, the G-BA provides access to all submitted German benefit assessments for pharmaceutical products on the G-BA's website.[1]

## OBJECTIVES

- The aim of this research was to assess the frequency and trend of the incorporation of Real World Evidence (RWE) studies in Modules 3 of value dossiers for estimating prevalence and incidence of the underlying disease and quantifying target populations after 10 years of AMNOG in Germany.
- Further objective of the research was to investigate the usage of different RWE data sources over time since the introduction of AMNOG in 2011.

## METHODS

- The study included all AMNOG value dossiers with publicly available benefit assessments between 01 January 2011 and 31 December 2021.
- Accordingly, all published Modules 3 of each value dossier were downloaded from the website of the G-BA.
- First, all Modules 3 were reviewed for the integration of RWE data regarding 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) used to determine epidemiological figures.
- The respective chapters 3.2.3/3.2.4 were searched for the following terms with the software R: *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).
- An additional hand search was conducted based on the previously identified study vendors/authors and methods used (49 search terms).
- Identified matches were verified by two independent reviewers through a full-text search of Module 3 chapters, and in addition, the corresponding chapters 3.2.5/3.2.6 were reviewed regarding information acquisition.
- For the analysis of trends in the frequency of integration of the respective data in value dossiers, the obtained screening results were analyzed for the years 2011 to 2021. The year of the first submission of RWE data was used as assessment year in case of multiple submissions for pharmaceutical products.
- The relevance of different data sources over time from 2011 through 2021 was explored for each data source category separately.

## RESULTS

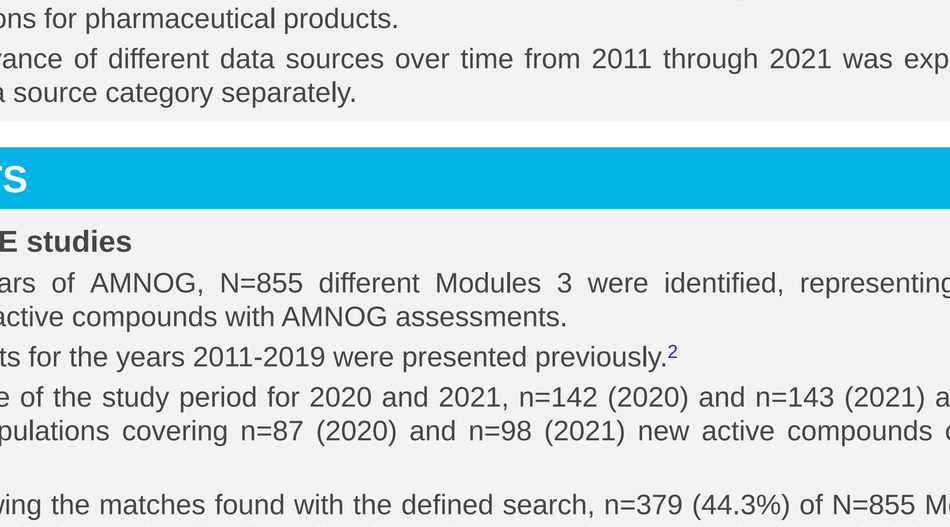
### Use of RWE studies

- In 10 years of AMNOG, N=855 different Modules 3 were identified, representing N=342 different active compounds with AMNOG assessments.
- The results for the years 2011-2019 were presented previously.[2]
- By update of the study period for 2020 and 2021, n=142 (2020) and n=143 (2021) additional target populations covering n=87 (2020) and n=98 (2021) new active compounds could be included.
- By reviewing the matches found with the defined search, n=379 (44.3%) of N=855 Modules 3 were identified as using RWE studies for estimating patient counts in the underlying disease and the target population.
- Based on active compounds, n=179 out of the total N=342 assessed pharmaceuticals (52.3%) made use of RWE studies.

### Indication areas with RWE data

- Most common indication areas applying RWE in Modules 3 included oncological (37.5%) and metabolic diseases (25.0%), followed by infectious diseases (8.1%) and diseases of the nervous system (7.0%) (see **Figure 1**).

**Figure 1. Indication areas with RWE data (N=379)**

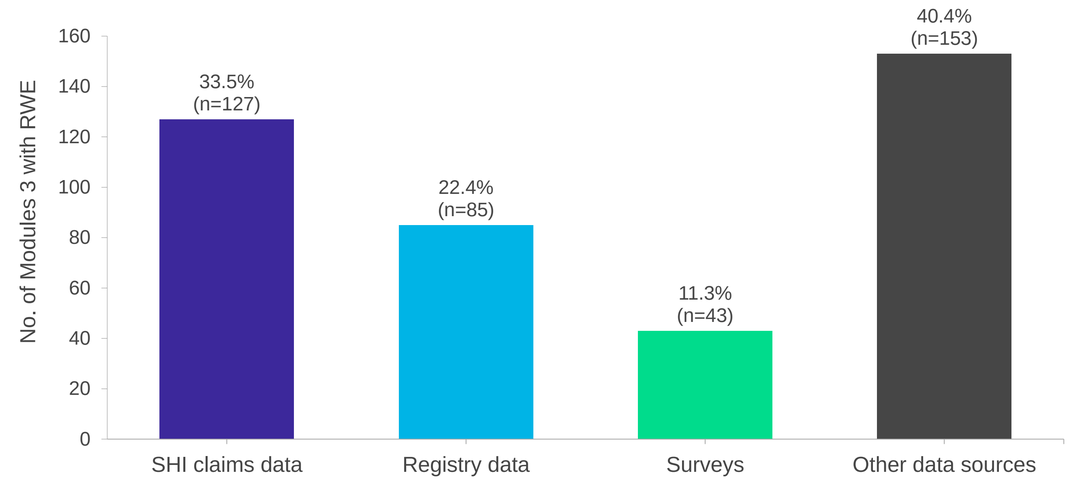



## RESULTS (CONTINUED)

### RWE data sources

- Among the N=379 Modules 3 incorporating RWE data, the most frequent source of RWE was other data (including chart reviews, outpatient practices data etc.) with n=153 (40.4%), followed by SHI claims data in n=127 (33.5%) Modules 3.
- Registry data were employed in n=85 (22.4%) and surveys were performed for n=43 (11.3%) Modules 3 (see **Figure 2**).

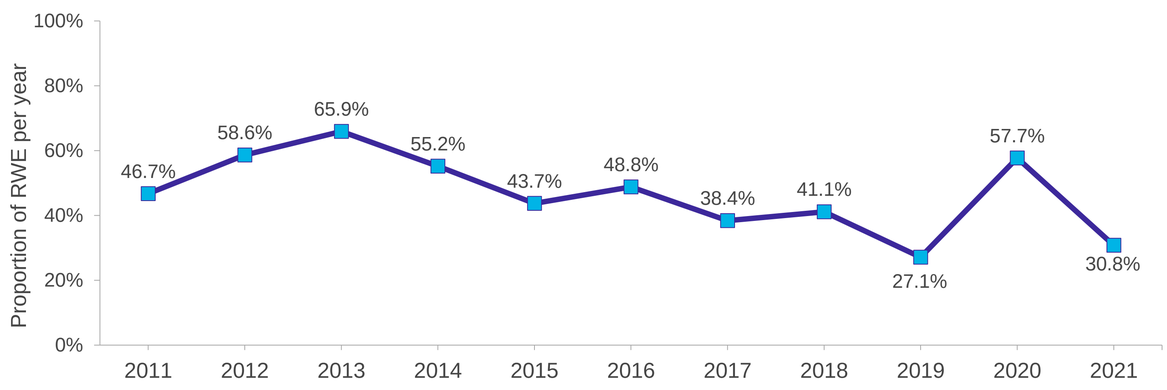
**Figure 2. RWE data sources (N=379)**




### Relevance of RWE over the course of time

- In 10 years of AMNOG, the integration of RWE studies in Modules 3 of German AMNOG value dossiers ranged between 27.1% (in 2019) and 65.9% (in 2013).
- Following a downward trend between 2013-2019, a sharp increase of RWE utilization was observable in 2020 (57.7%). In 2021, RWE studies were performed to quantify 30.8% of epidemiological measures (see **Figure 3**).

**Figure 3. Trend of RWE between 2011 and 2021**

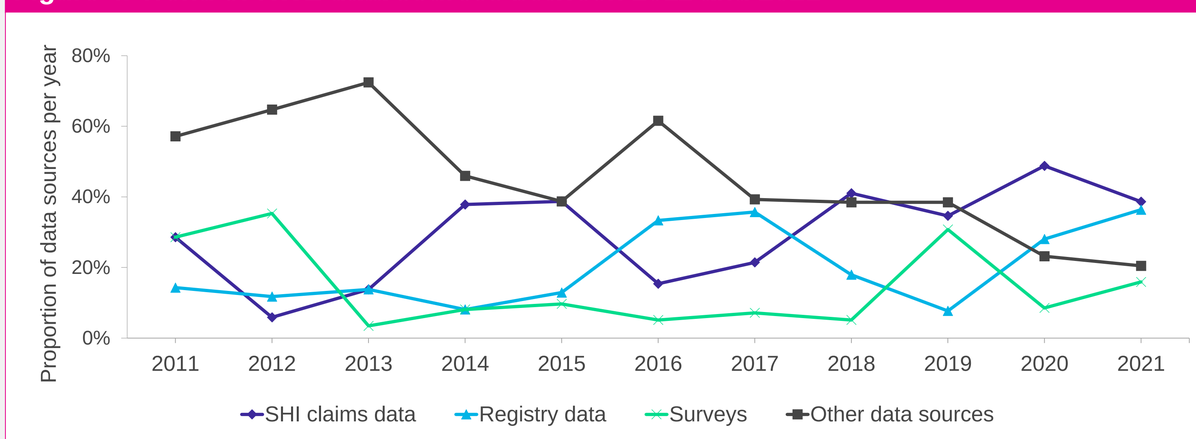



Note: Percentages are based on the number of RWE studies and the corresponding total number of Modules 3 in each year.

### Relevance of RWE data sources over the course of time

- For all RWE data sources, there were fluctuations regarding their relevance over time and no clear trend could be identified (see **Figure 4**).
- The use of health insurance claims data varied strongly between 2011 and 2021. In the most current years 2020 and 2021, SHI claims data were the most frequent source for RWE in published Modules 3, with 48.8% and 38.6% of all RWE data sources, respectively.
- Use of registry data peaked in 2017 with 35.7%, dropped in 2019 with 27.1%, and recovered in 2021 with 36.4%.
- Survey data accounted for the smallest share of all identified RWE data sources over the years, with a few exceptions (2011, 2012, and 2019).
- The use of other data sources declined from 2013 to 2021, except for 2016.

**Figure 4. Trend of RWE data sources between 2011 and 2021**




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

- Since the implementation of AMNOG in 2011, RWE studies have become a standard component in German AMNOG dossiers.
- The more balanced use of individual data sources for generating RWE highlights the various opportunities for supporting epidemiological considerations.
- Indication-specific SHI claims data analyses, registry studies, surveys, or other data analyses are valid and valuable data sources for the determination of epidemiological evidence, which offers a meaningful, more current, and complementary contribution to existing literature.

## REFERENCES

1. Gemeinsamer Bundesausschuss (G-BA). Nutzenbewertung von Arzneimitteln gemäß § 35a SGB V. 2019. https://www.g-ba.de/institution/themenschwerpunkte/arzneimittel/nutzenbewertung35a. Accessed October 1st, 2022.
2. Borchert K, Löpmeier J, Braun S, Jacob C (2019) The Relevance of Real World Evidence Studies in the German Benefit Assessment (AMNOG) Process. Paper presented at ISPOR 22nd Annual European Congress, Copenhagen, Denmark.

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