RELEVANCE OF REAL-WORLD DATA IN GERMAN AMNOG SUBMISSIONS IN ONCOLOGY

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BACKGROUND

- In Germany, pharmaceutical companies have to submit a benefit dossier to the Federal Joint Committee (G-BA) at market launch that contains data on prevalence, incidence, annual therapy costs, and medical benefits.[1]
- Real-world evidence (RWE) in Pharmaceuticals Market Reorganization Act (AMNOG) assessments potentially could address various data needs during the process and also thereafter, as epidemiology data might be limited in oncology.
- As about 87% of the German population is insured through the statutory health insurance, claims data can serve as an important source for RWE.[2]
- Areas of RWE use are evidence generation for epidemiology data (e.g., incidence, prevalence, unmet need) and the demonstration of effectiveness in daily life settings later on.

OBJECTIVE

- The aim of this study was to assess how RWE is currently integrated in German AMNOG submissions in oncology.

METHODS

- All commenced German AMNOG assessments until March 2017 were included in this analysis.
- Until June 2017, available dossiers were screened and evaluated if they related to any oncology field and if RWE on incidence or prevalence was implemented.
- The type of implemented RWE data was stratified by claims data; registry data; and other data sources such as IMS, Delphi panels, and Megapharm data.
- Findings were then analyzed and stratified by indication, and the applied data sources were described.
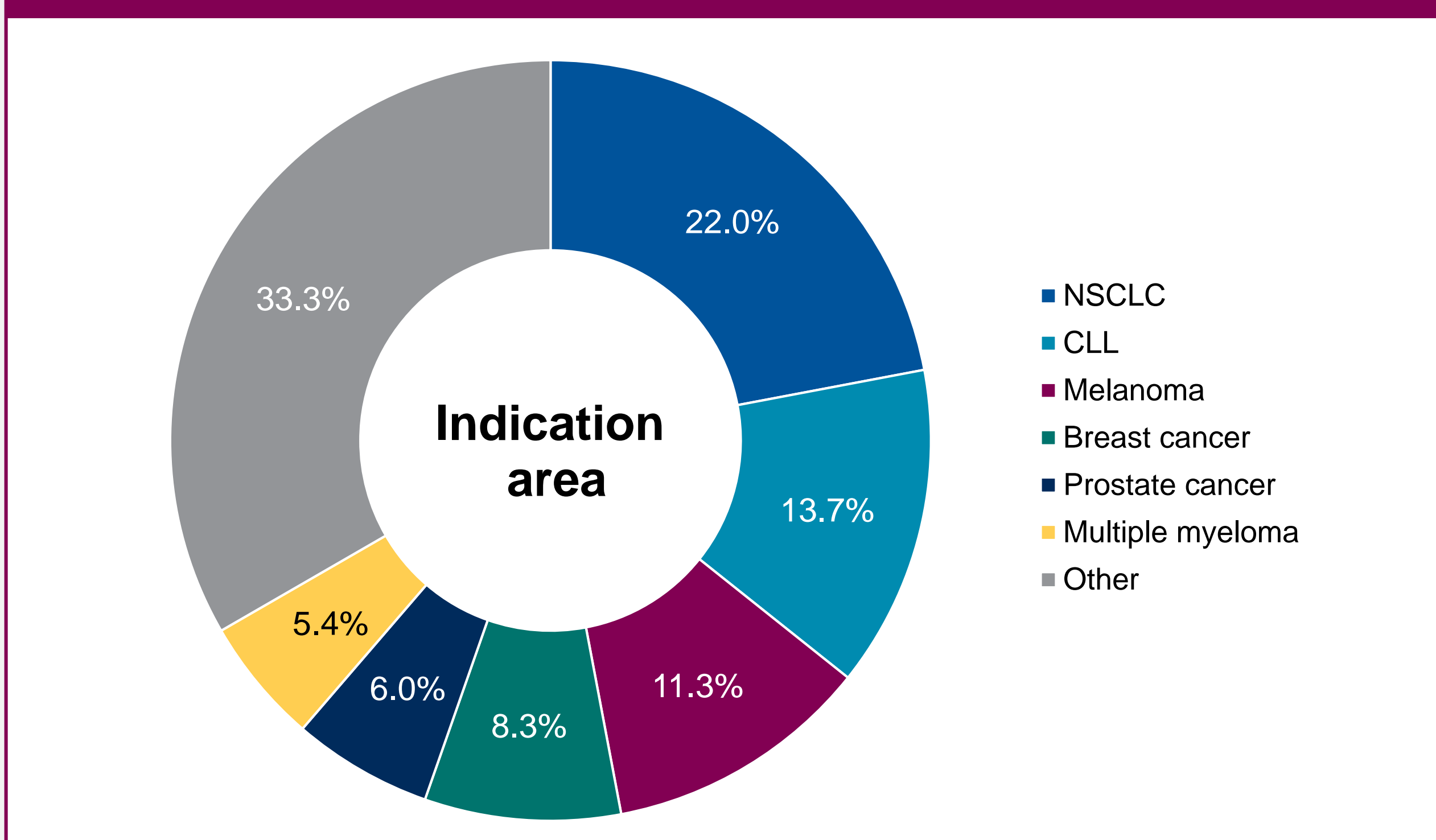
RESULTS

Subpopulations in Oncology

- In total, 273 AMNOG assessments were commenced until March 2017, comprising about 560 subpopulations.
- 95 (35%) AMNOG assessments were submitted in the field of oncology, which contained 168 subpopulations at the time of analysis.
- Per definition, more than one subpopulation is included if the drug is launched in ≥1 target application or if the G-BA stated additional benefits for different subgroups.

Disease Areas

- The most prevalent indication was non-small cell lung cancer (NSCLC) with 37 (22%) subpopulations, followed by chronic lymphatic leukemia (CLL) with 23 (14%) and melanoma with 19 (11%) (**Figure 1**).


Figure 1. Indication Areas of Oncological AMNOG Assessments

Indication area
- NSCLC — 22.0%
- CLL — 13.7%
- Melanoma — 11.3%
- Breast cancer — 8.3%
- Prostate cancer — 6.0%
- Multiple myeloma — 5.4%
- Other — 33.3%

Integration of RWE

- RWE for prevalence and incidence assessments was applied in 161 (95.8%) of the oncological subpopulations.
- Three dossiers were not available on the G-BA homepage at the time of evaluation, and the remaining four subpopulations did not include RWE data (**Figure 2**).
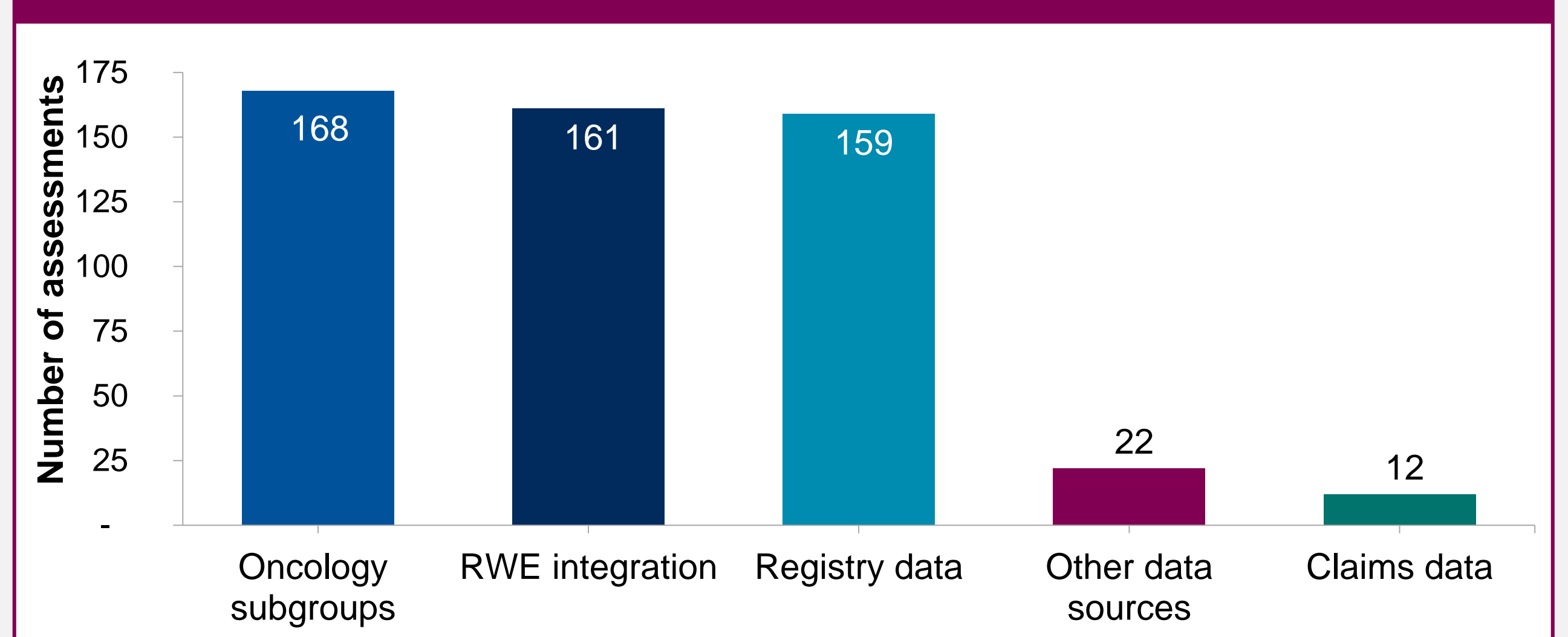

Figure 2. RWE Implementation in Oncological AMNOG Assessments

Integration of RWE
- RWE data — 95.8%
- No RWE data — 2.4%
- Dossiers not available — 1.8%
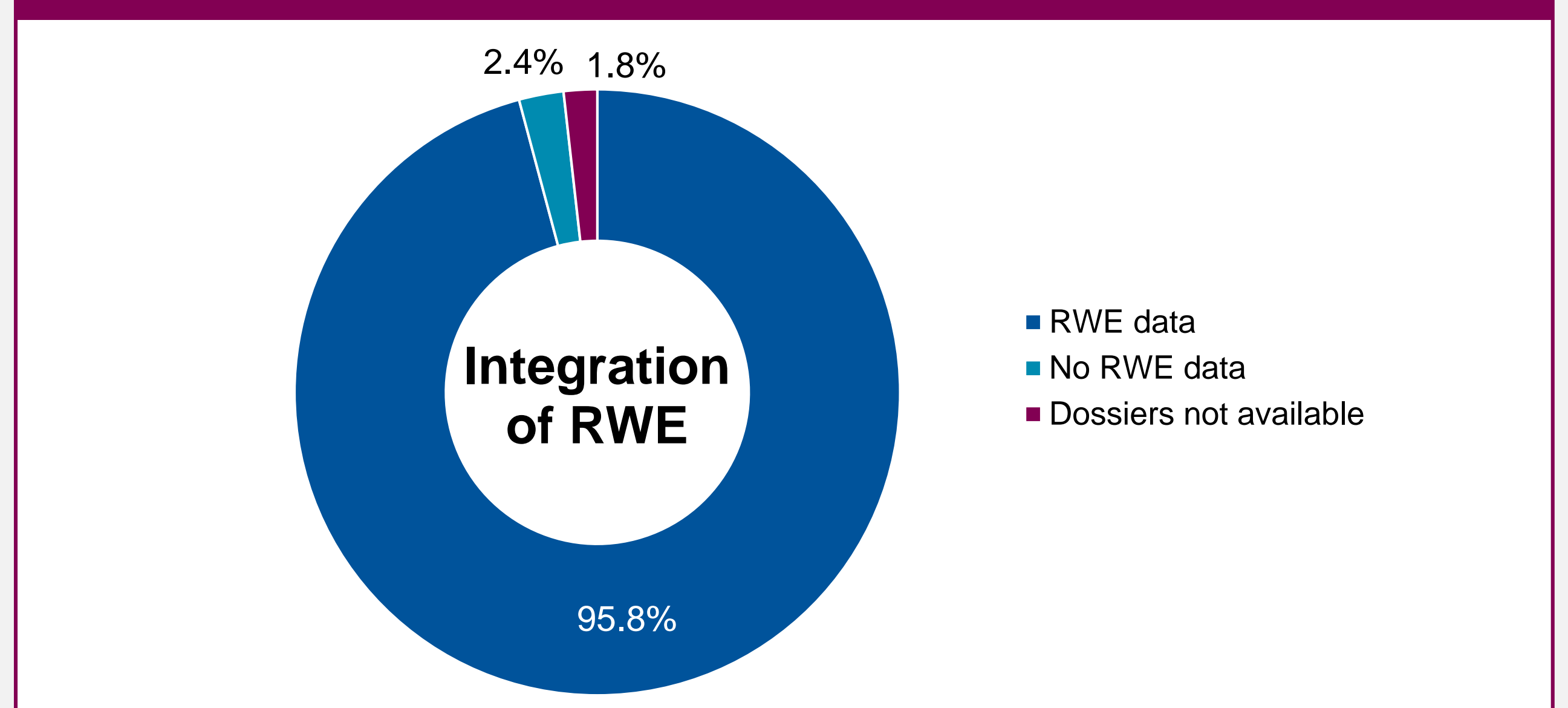
Types of RWE Data

- The use of claims data was reported in 12 (7.5%) subpopulations; 159 (98.8%) used registry data; and 22 (13.7%) used other data sources such as IMS data, Delphi panels, Kantar Health data, Insight Health data, and Megapharm data (**Figure 3**).
- As it is possible to use multiple assessments for one dossier, in 32 (19.9%) subpopulations, more than one RWE data source was integrated.

Figure 3. Data Sources of RWE in Oncological AMNOG Assessments

Category	Number of assessments
Oncology subgroups	168
RWE integration	161
Registry data	159
Other data sources	22
Claims data	12

Pipeline Products

- For the German market, about 960 products are currently in the pipeline for the oncological therapeutic area with the proposition to be launched in Germany by the respective pharmaceutical company. Of those, 88 products are in phase 1, 312 in phase 2, and 143 in phase 3. Four drugs were pending approval at the time of analysis.[3]

CONCLUSIONS

- RWE is commonly used in AMNOG assessments in oncology, forming an integral part of the epidemiology section of the available evidence package.
- Registry data are currently the data source that is applied predominantly.
- Claims data are becoming an important data source, adding evidence on epidemiology in German AMNOG assessments.
- New products in the pipeline will create additional needs for epidemiological insights from various data sources to inform future AMNOG dossiers.

REFERENCES

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