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BACKGROUND

- With the Act on the Reform of the Market for Medicinal Products (AMNOG) regulation in 2011, new Health Technology Assessment standards were introduced in Germany.
- Under AMNOG, pharmaceutical companies need to describe the benefit of their pharmaceuticals in a value dossier which is submitted to the Federal Joint Committee (G-BA) at market launch.
- A requirement of Module 3 of each value dossier is to state (in tabular form) whether and, if so, which significant changes in terms of prevalence and incidence of the underlying disease are to be expected in Germany within the next five years.
- Since the introduction of AMNOG, all benefit assessments of pharmaceutical products are publicly accessible on G-BA's website.¹

OBJECTIVES

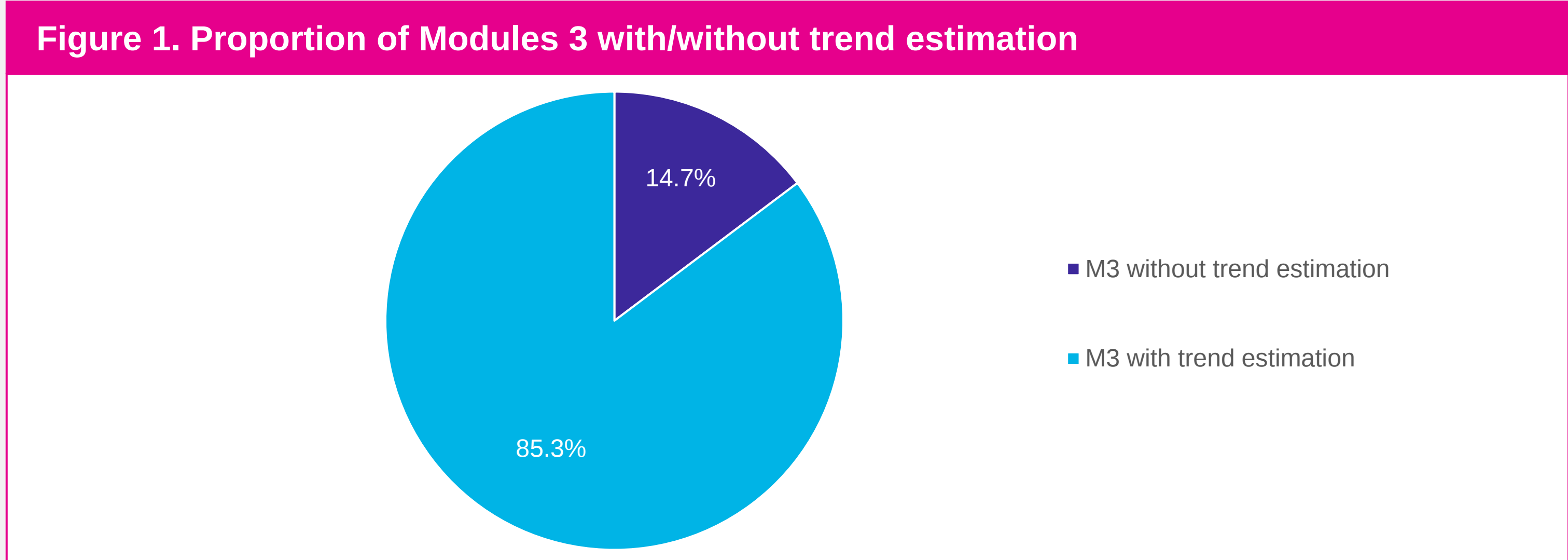
- Aim of this study was to identify methods used in German AMNOG value dossiers to estimate the development of prevalence and incidence of the underlying disease over the next five years and thereby to explore the relevance of different trend estimation methods.

METHODS

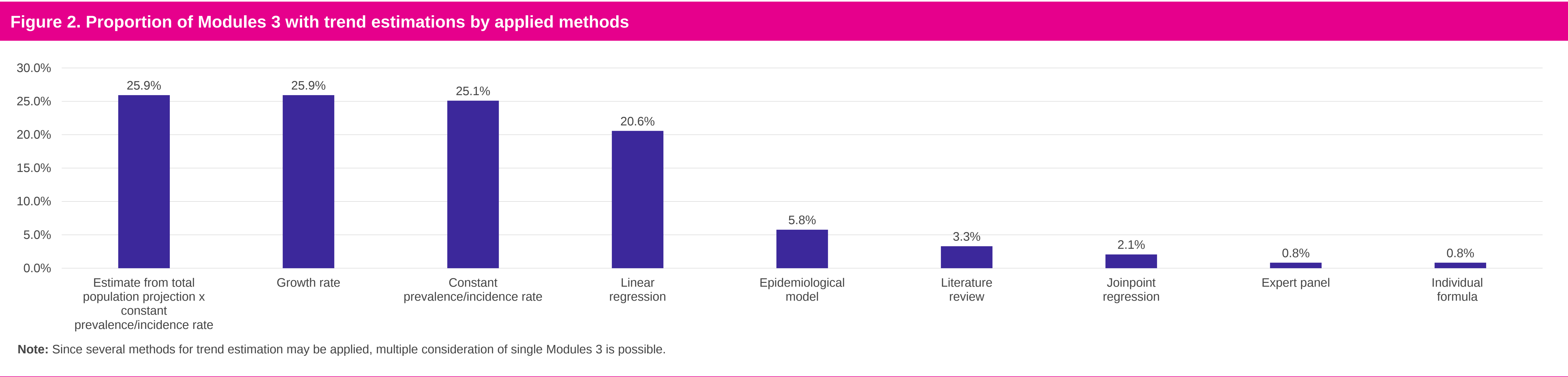
- All AMNOG value dossiers published in the years 2020 and 2021 were included in the analysis and all corresponding Modules 3 of each active substance were downloaded from the G-BA's website.
- The epidemiological section of each value dossier (section 3.2.3 of Module 3) was reviewed to determine whether a trend estimation describing the development of prevalence and/or incidence in the upcoming five years was performed.
- For dossiers including a trend estimation, the applied methods used were recorded and categorized.
- Two independent reviewers verified the categorization of the applied methods.
- Results were stratified for indication areas.

RESULTS

- A total of N=285 Modules 3 were submitted until December 31st, 2021, representing N=163 different active compounds with AMNOG assessments.
- Most prominent indication areas were oncological diseases (38.2%), metabolic disorders (18.9%), and infectious diseases (9.5%).
- Trend estimations for prevalence and/or incidence were performed in 85.3% (n=243) of Modules 3 (see **Figure 1**).



- Identified methods applied for trend calculation included e.g., literature review, epidemiological modelling, regression, mean or growth rate of prevalence/incidence rates, and projections of the total population.
- The use of single prevalence/incidence rates to forecast the prevalence/incidence of underlying diseases, which are based on one (e.g., single value of last measured year) or several years (e.g., mean rate across the last years), was categorized as trend estimation method 'constant prevalence/incidence rate'.
- Literature review as method of trend estimation was chosen when projections were taken from the published literature (e.g., GLOBOCAN²) or when external sources that already included trend estimates were referenced.
- Most commonly, trends were determined based on constant prevalence/incidence rates (25.1%), often combined with the German population forecast of the Federal Statistical Office of Germany (DESTATIS) (25.9%), on growth rates (25.9%), or linear regressions (20.6%) (see **Figure 2**).
- Mean prevalence/incidence rates of the past years were calculated in 17.7% of the included Modules 3 with trend estimation.
- In n=6 (2.5%) Modules 3, trend estimation was performed without describing the applied method.

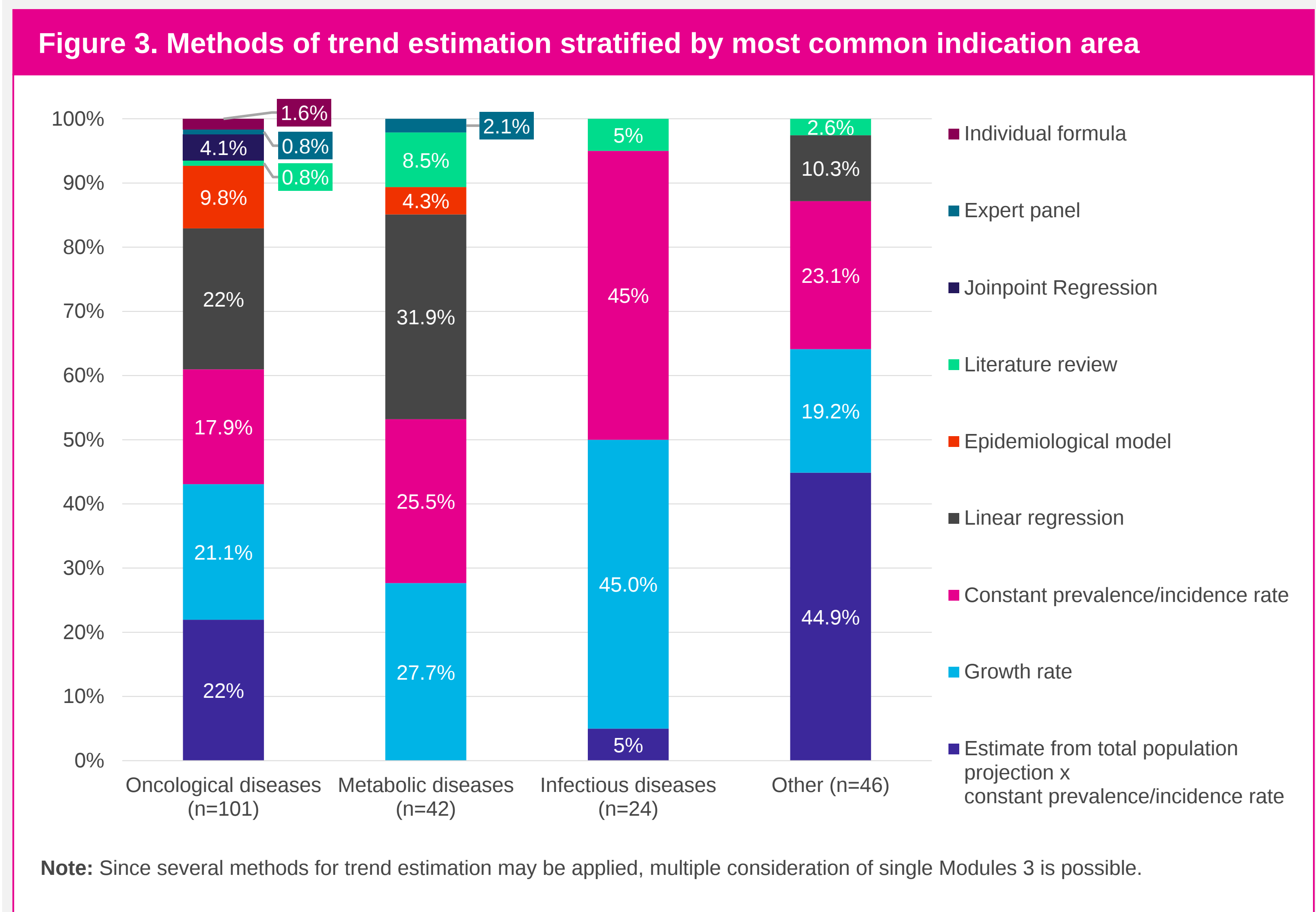


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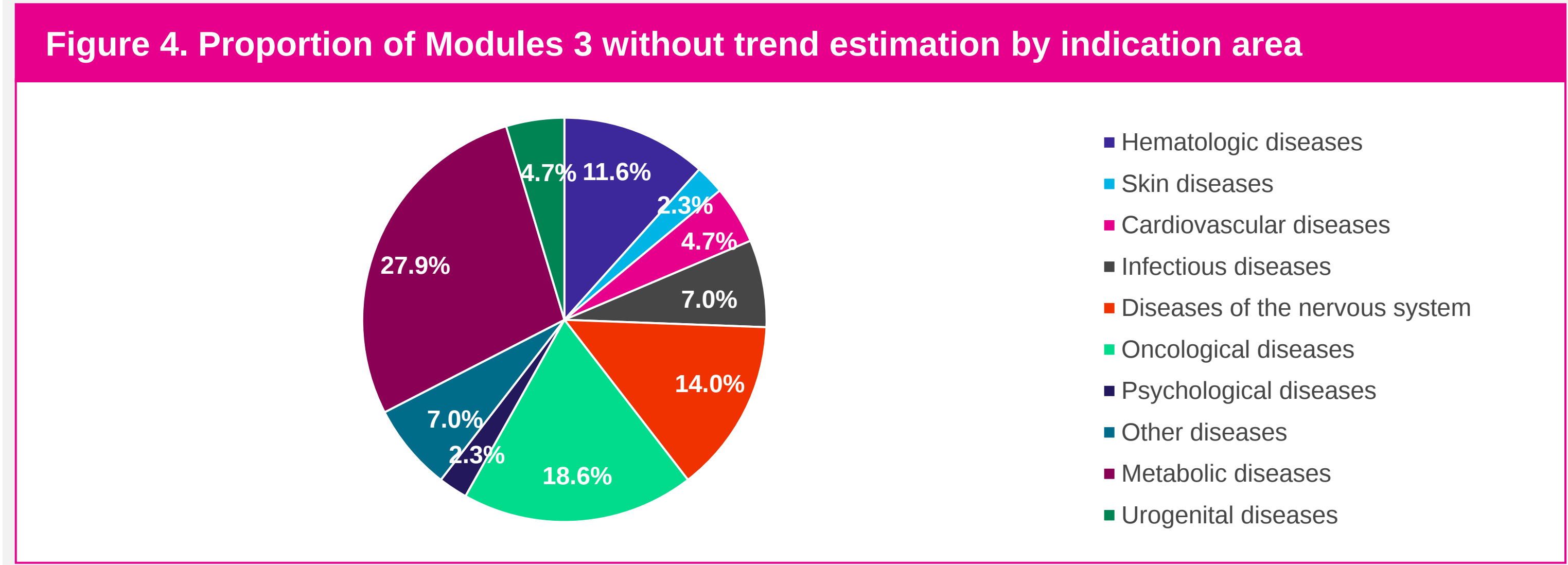
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RESULTS (CONTINUED)

- Figure 3** shows the stratification of applied methods by most common indication area.
- Differences in the use of the trend estimation methods were revealed between the investigated indication areas.
- Growth rates (17.7-45.0%) and constant prevalence/incidence rates (19.2-45.0%) were frequently used in each of the most common indication areas, while linear differences.



- The most frequent indication areas without trend estimation (see **Figure 4**) were metabolic (27.9%) and oncological diseases (18.6%), as well as diseases of the nervous system (14.0%).
- Approximately one-third of these Modules 3 concerned orphan drugs (31.0%). Thus, published data on disease prevalence/incidence rates are limited or insufficient for draw valid conclusions about future trends.
- A prominent argument given in cases of missing trend estimates was that no significant change in the prevalence/incidence of the underlying disease was expected in Germany for the next five years (e.g., due to a lack of biologically or epidemiologically plausible reason for any changes).



CONCLUSIONS

- The requirements for trend estimations in Module 3 according to the G-BA's Rules of Procedure on the benefit assessment of pharmaceuticals pursuant to § 35a SGB V are fulfilled in the majority of AMNOG dossiers.
- A wide range of methods spanning from simple literature research to multiple regression models are applied to forecast the development of underlying diseases in the upcoming five years.
- Most commonly, trend estimation was based on constant prevalence/incidence rates, often combined with the German population forecast, on growth rates, or on linear regression.