Developments in benefit dossiers and assessments by IQWiG of the G-BA

Effects of the new dossier requirements

Since 2011, pharmaceutical companies in Germany have been obliged to submit an AMNOG benefit dossier to the G-BA when a new medicinal product enters the market or has its marketing authorisation extended. On the basis of the IQWiG benefit assessment, the G-BA makes an assessment of the added benefit of the medicinal product and follows the assessment by IQWiG for the most part. In April 2020, a revised, currently valid dossier template for Module 4 came into force, which drastically increases the already large presentation effort for pharmaceutical companies. However, with increased presentation effort, a considerable proportion does not appear to be relevant to the conclusion for the additional benefit awarded by the G-BA. In an efficient AMNOG process, only evaluations with actual added value should be made mandatory in future.

>> In April 2020, a revised dossier template for module 4 came into force (Federal Joint Committee, 2019), which imposed a number of additional requirements on data preparation and significantly increased the scope of this module compared to the previous dossier template (Federal Joint Committee, 2013) (Bartol et al., 2022). The current requirements include, among others, the presentation of additional data sections for all endpoints (EPs), detailed evaluations of EPs for adverse events (AEs) as well as subgroup (SG) analyses for all EPs (Verband Forschender Arzneimittelhersteller, 2021). These adjustments were intended to increase the traceability of the available data and to align the quality of the assigned information between the benefit dossiers (Federal Joint Committee, 2019).

The sharp increase in requirements led to an increasing scope of Module 4 and is associated with a considerable additional effort and additional resource consumption for the German health care provider, IQWiG and the Federal Joint Committee (Verband Forschender Arzneimittelhersteller, 2021). A large part of the information submitted is not taken into account in the benefit assessment procedure, as an analysis of ten procedures with current dossier submissions by the Association of Research-Based Pharmaceutical Companies (vfa) was able to show as early as 2021 (Verband Forschender Arzneimittelhersteller, 2021).

It is clear that IQWiG already presented less for a large number of endpoints on adverse events and subgroups than was submitted by the pharmaceutical companies. This discrepancy increases with the current dossier submission. With an increased presentation effort for the pharmaceutical companies, a considerable proportion of the additionally submitted endpoints on adverse events and subgroups do not seem to be relevant to the conclusion of the added benefit. Only serious adverse events and serious adverse events as well as the subgroups age, gender and disease severity seem to be relevant.

In general, it is not clear which objective criteria IQWiG and the Federal Joint Committee use to select the endpoints on adverse events and subgroups that are relevant for the assessment. In an AMNOG process that is efficient for all parties involved, only evaluations with actual added value should be presented as mandatory in future. An adaptation of the dossier template to this effect seems urgently required.

Question

In view of the greatly increased requirements within the framework of the benefit dossier, the fundamental question arises as to which data are necessary and sufficient for an efficiently designed benefit assessment that ensures a high degree of transparency on the part of the company on the one hand, and a high quality of the assessment by IQWiG and the decision by the Federal Joint Committee on the other. Specifically, the present analysis therefore poses the question of how the additional data required in the current dossier submissions in Module 4 are actually taken into account in the assessment.

Within the scope of this question, the proportion of the data evaluations required by the company is systematically examined in the IQWiG benefit assessment. In addition, it is analysed how this proportion has changed with the current dossier submission compared to the old one and to what extent the required evaluations are explicitly relevant to the conclusion for the determination of the ZN by the G-BA. The focus of the analyses is on the evaluations of UE and SG, as the most far-reaching changes were made in these two areas.

Background

SSince the introduction of the German Pharmaceutical Market Reorganisation Act (AMNOG) in 2011, pharmaceutical companies (pU) in Germany are obliged to submit a dossier for the benefit assessment according to Section 35a of the German Social Code, Book V (Bundestag, 2010) when placing new medicinal products on the market or extending a marketing authorisation. On the basis of this benefit dossier and on the basis of the dossier evaluation by the Institute for Economic Efficiency in Health Care (IQWiG), the Federal Joint Committee (G-BA) decides on an additional benefit (ZN) of the medicinal product to be evaluated (zbAM) compared to a comparator defined by the G-BA, the appropriate comparator therapy (zVT). For the preparation of the benefit dossier, which is composed of five different modules, predefined document templates must be used (Federal Joint Committee, 2022). These dossier templates request different information on the zbAM. Module 4 in particular requires extensive and very detailed preparation of study data and analyses by the company.

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Methods

To answer the questions, the benefit dossiers of the company, the associated benefit assessments of IQWiG, as well as the decision texts and supporting reasons of the Federal Joint Committee (G-BA) were examined with regard to the presented EPs on AEs and SG characteristics. For this purpose, procedures were selected based on old and current dossier submissions. Subsequently, data relevant to the investigation of the research question on the primary data section considered in the benefit assessment procedure were extracted from the documents of the company, IQWiG and the Federal Joint Committee described above.

Selection of procedures

The selection of trials based on the current dossier template included all trials with a trial start date from 01.04.2020 (publication of IQWiG benefit assessment 01.07.2020 to 15.06.2021, G-BA decision text and TrG from 17.09.2020 to 15.09.2021). The selection ofprocedures based on the old dossier template included procedures up to 01.04.2020. For better comparability of the procedures, care was taken to assign to each procedure with a current dossier template as current a counterpart as possible of a procedure with an old dossier template in a comparable indication area or comparable research question. In order to fully investigate the requirements of the dossier template, orphan drug procedures, procedures with single-arm studies, procedures in which no data were regularly submitted (in particular with regard to UE and SG analyses) or assessed by the G-BA were excluded. If it only became apparent in the course of data extraction that no usable data were available for a procedure, an attempt was made to find a suitable alternative according to the same criteria. For two procedures according to the current dossier template, no suitable procedure according to the old dossier template could be identified.

Data extraction and quality assurance

For the data extraction, a reviewer extracted the information on evaluations of UE-EP or information on SG in the benefit dossiers of the company as well as in the benefit assessments or addenda of IQWiG and the decisions or TrG of the Federal Joint Committee. The quality control of the extraction was performed by a second independent reviewer. Discrepancies were consolidated jointly by both reviewers. In addition to superordinate, general information such as product name, date of the G-BA decision or whether the old or current dossier template was used, data on the AEs and SGs were primarily collected. With regard to AEs, the number of AE-EPs differentiated according to different categories and severity as well as SOC, PT and the number of adverse events of special interest (UESI) were recorded. For IQWiG benefit assessments, the EPs on AEs were extracted from the results section including the appendix tables. For the SGs, the presentation of the mandatory SG characteristics age, sex, ethnicity/region and disease severity, as well as any other SG characteristics presented, was recorded. In addition, it was investigated whether the data recorded for AEs and SGs were also assessed as relevant to the conclusion for the determination of the CN. If the company presented data for different study phases, the data representing the entire study period were extracted. If the G-BA derived the ZN on the basis of a meta-analytical summary of several studies or an indirect comparison, only the data of the meta-analysis or the indirect comparison were extracted. If several non-meta-analytically summarised studies were presented in one procedure, then, if only one study was presented in the partner procedure, only the data of the study that was most similar to the study of the assigned partner procedure with regard to design, patient numbers, etc. were extracted.

Zusammenfassende Übersicht der Darstellung der EP zu UE in Nutzendossier und Nutzenbewertung des IQWiG

	Alte Dossiervorlage[1]			Aktuelle Dossiervorlage[2]		
Endpunktkategorie Anzahl der EP	**Dargestellt pU**	**Dargestellt IQWiG**	**Differenz** (jeweils bezogen auf den Median)	**Dargestellt pU**	**Dargestellt IQWiG**	**Differenz** (jeweils bezogen auf den Median)
Jegliche UE nach SOC/PT						
Median Mittelwert Min; Max	24 74 (0; 705)	27 40 (0; 197)	**-3**	59 109 (2; 1376)	49 70 (0; 718)	**10**
SUE nach SOC/PT						
Median Mittelwert Min; Max	3 13 (0; 109)	3 9 (0; 107)	**0**	5 17 (0;382)	5 7 (0; 30)	**0**
Schwere UE nach SOC/PT						
Median Mittelwert Min; Max	2 14 (0; 101)	0 7 (0; 49)	**2**	15 30 (0; 574)	2 10 (0; 38)	**13**
Nicht-schwere UE nach SOC/PT						
Median Mittelwert Min; Max	0 39 (0; 859)	0 0 (0; 0)	**0**	0 14 (0; 91)	0 0 (0; 0)	**0**
Abbruch aufgrund UE nach SOC/PT						
Median Mittelwert Min; Max	0 16 (0; 126)	8 29 (0; 127)	**-8**	48 54 (0; 246)	32 32 (0; 95)	**16**
UESI						
Median Mittelwert Min; Max	17 21 0; 90	6 8 0; 30	**11**	24 28 0; 144	7 9 0; 36	**17**
Alle EP zu UE (inkl. SOC/PT)						
Median Mittelwert Min; Max	69 177 (8; 1801)	72 94 (0; 363)	**-3**	181 252 (7; 2590)	122 127 (4; 822)	**59**

[1] alte Dossiervorlage: gemäß Beschluss vom 18. April 2013.
[2] aktuelle Dossiervorlage: gemäß Beschluss vom 21. Februar 2019, In Kraft getreten im April 2020.

EP: Endpunkt; IQWiG: Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen; PT: Preferred Term; pU: pharmazeutischer Unternehmer; SOC: System Organ Class; SUE: schwerwiegende unerwünschte Ereignisse; UE: unerwünschte Ereignisse.

Tab. 1: Summary overview of the presentation of the EPs on AEs in the benefit dossiers of the company, the benefit assessments of IQWiG, and the difference between the two. A distinction is made in each case between the old and current dossier submission.

Statistical analyses

The analysis of the data was descriptive. For categorical data, frequencies and percentages of the respective categories were reported. For continuous data, descriptive parameters such as median, arithmetic mean, minimum and maximum were presented. The analyses were performed separately for the respective institutions pU, IQWiG and G-BA, and separately for the old and current dossier submission.

For the descriptive analysis of the total presentation effort for AEs and for SGs, the variables ‚All AE endpoints (incl. SOC/PT)' and ‚Total number of SG characteristics' were created. The first variable included a sum of the number of all AEs of any severity, SUE, severe AE, non-severe AE, discontinuation due to AE by SOC and PT, and all non-severe, severe and severe UESI. The second variable included a summation of all SG characteristics presented.

Results

The present analysis investigated which proportion of the data analyses requested by the company were presented in IQWiG's benefit assessment (IQWiG's perspective) and to what extent the requested analyses were explicitly relevant for the determination of the benefit assessment (G-BA's perspective). Furthermore, it was analysed how the proportion of analyses considered changed with the current dossier submission compared to the old one for all parties involved (pU, IQWiG and G-BA).

IQWiG's perspective

A total of 94 procedures were selected for the comparison of dossier requirements. Of these, 46 were based on the old dossier template (Federal Joint Committee, 2013) and 48 on the current dossier template (Federal Joint Committee, 2019). The indication areas included oncological diseases (47 procedures in total), diseases of the respiratory system (n = 19), the musculoskeletal system (n = 7), the nervous system (n = 3) as well as mental diseases (n = 2), cardiovascular diseases (n = 2), infectious diseases (n = 5), skin diseases (n = 4), metabolic diseases (n = 4) and eye diseases (n = 1). Within the indication areas, the distribution between procedures based on the old vs. the current dossier template was comparable.

Table 1 provides an overview of the number of EPs on AEs presented by the company and IQWiG for the old and the current dossier template. Compared to the old dossier submission, the median number of presentations in the current dossier submission has multiplied for almost every AE endpoint category. In addition, there was a discrepancy between the presentation effort of the company and that of IQWiG, particularly for the current dossier submission. Only for the endpoint categories SUE according to SOC/PT and non-severe AE according to SOC/PT was the median ratio of presentations mathematically balanced, but the latter category was generally not presented by IQWiG. In contrast, a maximum of up to 91 non-severe AEs according to SOC/PT were presented for the company under the current dossier submission.

Endpoints on adverse events

Table 1 shows a summary overview of the presentation of AEs in the benefit dossiers of the company and the benefit assessments of IQWiG, as well as the difference between the two. A distinction is made between the old and the current dossier template.

Using the current dossier template, the company presented a median of 20% more evaluations than IQWiG for any AEs after SOC/PT. IQWiG even presented a median of 87% fewer evaluations for severe AEs after SOC/PT compared to the company. With the old dossier submission, a maximum of 101 serious AEs according to SOC/PT were submitted; with the current dossier submission, up to 574 evaluations were submitted for this EP category. IQWiG, on the other hand, presented a maximum of less than 50 serious AEs after SOC/PT under both the old and current dossier templates. In the category discontinuation due to AEs after SOC/PT, IQWiG provided a median of only two-thirds of the evaluations compared to the company. The picture was particularly drastic for UESI, where IQWiG's median presentation effort fell to less than one third compared to the company. In the analysis of all EPs on AEs, including all SOCs and PTs, the number of presentations for the company almost tripled in comparison with the old and current dossier submission. IQWiG, on the other hand, saw an increase of only 69%. Thus, IQWiG presented only 67% of the median number of evaluations in this category compared to the company. The range of presentations also illustrated the discrepancy between the two parties. While the maximum number of EPs presented by the company for the category All EPs for AEs including SOC/PT was 2590, the maximum number of EPs presented by IQWiG was only 822.

Subgroups

The dossier submission calls for a mandatory presentation of SG analyses for the SGs age, gender, ethnicity/region and disease severity. Accordingly, these SGs are to be regularly presented by the company in the benefit dossiers. Accordingly, in the 46 evaluated procedures with an old dossier template and the 48 evaluated procedures with a current dossier template, these SGs were presented in more than 95% of the benefit dossiers.

Table 2 shows the total number of SG characteristics represented. With the change to the current dossier template, the median number of SG characteristics presented increased slightly for the company, but decreased slightly for IQWiG. For the current dossier template, IQWiG presented only 27% of the SG characteristics compared with the company. The difference in presentation effort was also apparent from the maximum number of SG characteristics presented, which was 24 for the company and only 6 for IQWiG. In addition, the number of SG characteristics must be interpreted in the context of the strong increase in EPs (for which SG analyses are calculated). Thus, the slight increase in the number of SG characteristics is potentiated by the strong increase in the number of EPs presented, which leads to a strongly increased number of SG analyses in total.

For the current dossier submission, the SG age was considered in 81% of the cases in IQWiG's benefit assessment. The SG gender was considered in 73% of the cases. While IQWiG still considered the SG ethnicity/region submitted by the company in 61% of the cases using the old dossier template, the relative number of representations considered using the current dossier template decreased to 23%. Consequently, for the current dossier template, three quarters of the representations for this SG were not considered in the IQWiG benefit assessment. The SG disease severity was considered by IQWiG in almost half of the cases (48%) for the current dossier submission.

In addition to the SGs mentioned above, the company is required to present results

Zusammenfassende Übersicht der Darstellung der Ergebnisse zu SG-Analysen in Nutzendossier und Nutzenbewertung des IQWiG

	Alte Dossiervorlage[1]			Aktuelle Dossiervorlage[2]		
	Dargestellt pU	**Dargestellt IQWiG**	**Differenz** (jeweils bezogen auf den Median)	**Dargestellt pU**	**Dargestellt IQWiG**	**Differenz** (jeweils bezogen auf den Median)
Gesamtanzahl der SG-Merkmale						
Median	10	4	**6**	11	3	**8**
Mittelwert	10	4		11	3	
Min; Max	(0; 22)	(0; 8)		(0; 24)	(0; 6)	

[1] alte Dossiervorlage: gemäß Beschluss vom 18. April 2013.
[2] aktuelle Dossiervorlage: gemäß Beschluss vom 21. Februar 2019.

IQWiG: Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen; pU: pharmazeutischer Unternehmer; SG: Subgruppen.

Tab. 2: Total number of SG characteristics presented. The SG analyses presented by the company in the benefit dossier and by IQWiG in the benefit assessment are compared, as well as the difference between the two. A distinction is made between the old and the current dossier submission.

of SG analyses for patient-relevant outcomes that are planned a priori and specified in the study protocol (Federal Joint Committee, 2021). Further analyses showed that outside of the above-mentioned median SGs, no other SGs were considered by IQWiG in the benefit assessment. This applies to both the old and the current dossier submission. In isolated cases, evaluations of disease-specific SGs were taken into account in the other SG characteristics.

Table 2 shows the total number of SG characteristics presented. The SG analyses presented by the company in the benefit dossier and by IQWiG in the benefit assessment are compared, as well as the difference between the two. A distinction is made between the old and the current dossier submission.

Perspective of the G-BA

The analysis of all 94 selected assessment procedures showed that the G-BA follows IQWiG in the TrG with regard to the selection of the UE-EP presented in most cases (76%). Considered separately, the values for procedures with an old and a current dossier template are comparable. Isolated AEs that show a statistically significant effect are occasionally presented in support of the assessment and derivation of the ZN. A comparison showed that the use of the current dossier template increased the proportion of these supportively presented AEs that were included in the consideration of the ZN (43% vs. 56%).

IQWiG's selection of SG age, sex, ethnicity/region and disease severity was adopted by the G-BA in at least half of the cases in both procedures with an old and a current dossier template and was mostly not commented on in the TrG (93% vs. 85%). In the majority of cases, the selection of the SG was not relevant to the conclusions of the ZN awarded by the G-BA (72%), and in 18% of the cases an evaluation of the data was not possible. Considered separately, comparable values resulted in this respect for procedures with old and procedures with current dossier submission (76% vs. 69%).

Discussion

Discrepancies between presented and evaluated analyses

The additional analyses required in the current dossier submission result in an increased analysis and presentation effort of UE-EP and SG for the company. The dossier evaluation also becomes more time-consuming for IQWiG and partly for the G-BA. Particularly in the EP categories of serious AEs, UESIs and all EPs on AEs, in each case according to SOC/PT, an in part significantly increased analysis and presentation effort can be seen. The present analysis impressively illustrates a large discrepancy between the number of EPs submitted by the company and the number of EPs assessed in IQWiG's benefit assessment. These results are in line with the results of a study conducted in 2021 (Verband Forschender Arzneimittelhersteller, 2021) and, in addition to a considerably larger number of procedures, also provide up-to-date findings in the comparison of the old and current dossier template. Even in the old dossier template, IQWiG often did not take into account the UE analyses presented. This gap has widened further with the introduction of the current dossier template. With regard to the presentation of SG characteristics, the present analysis also shows that more SGs are presented by the company in both the old and the current dossier submission than are presented in the IQWiG benefit assessment. Since the majority of the G-BA follows IQWiG's assessment, there were already non-factor-relevant evaluations in the old dossier submission, the number of which increased further with the current submission.

Conceivable approaches for a more efficient Module 4 as part of a ‚learning system

The German benefit assessment process was already considered to be incomparably extensive before the introduction of the current dossier template (Ivandic, 2014) and the German benefit assessment procedure has been described by those responsible since its start as a ‚learning system' (Bokemeyer C., 2017), which is constantly modified and further developed in details (Federal Joint Committee, 2019).

As can be seen from the present analysis, the current AMNOG process is overall more inefficient than before the change in April 2020, so that an adjustment of the dossier template seems to be called for.

For the assessment and derivation of the ZN, occasional isolated AEs that show a statistically significant effect are presented in a supportive manner. However, mandatory UE-EP, such as non-severe UE and any UE after SOC/PT, do not appear relevant for the ZN derivation. Removing the general obligation to present these UE-EPs therefore seems logical. With regard to the scope of the UESI to be presented by the company, it also remains unclear on the basis of which objective criteria or which methodology IQWiG selects the UESI for the benefit assessment using the event frequencies that occurred in the studies. IQWiG's approach here is not entirely based on a medical or biometric rationale. While the obligation to present prespecified, i.e. medically or biologically justified UESI is correct and comprehensible, the obligation to present UESI not predefined in the study programme according to severity should be omitted altogether. A mere signal detection is not meaningful in the context of the benefit assessment.

In addition to the SG characteristics defined in the rules of procedure of the G-BA, gender, age, disease severity, severity or disease stage as well as country and study centre effects (Federal Joint Committee, 2022), further pre-specified SGs are added individually for each trial.

According to the dossier template, analyses for all safety EPs incl. UESI, SOC/PT (in the case of significant SOC or PT) must be submitted for all these SGs, which multiplies the necessary UE analyses once again for each additional SG. A resolution breakdown according to SG characteristics is extremely rare in this case and subgroup effects in individual UE according to SOC and/or PT did not play a conclusion-relevant role for the resolution. The present analysis underlines that a blanket obligation to present all pre-specified SG analyses for all endpoints should be dispensed with. It is particularly clear from the SG ethnicity/region that both with the old and the current dossier submission, more SGs are submitted by the company than are presented by IQWiG in the benefit assessment procedure. The significance of these SGs has clearly decreased with the current dossier submission. In contrast, the SGs age, sex and, in some cases, disease severity appear to be particularly relevant. Other SG characteristics only play a role in isolated cases. A central point for the definition of SG in the context of the benefit assessment is the external evidence, i.e. the biological or sociological rationale (DGHO, 2016). However, precisely because of their lack of biological and biometric rationale, the SGs presented are usually not included in the discussion on the derivation of the ZN.

Currently, it is not clear why and under what conditions the requested analyses on AEs and SGs are not taken into account by IQWiG and the G-BA. Since the G-BA does not comment on non-conclusion-relevant AEs and SGs in its decision, it also remains

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unclear to what extent these data are required or used for the assessment of the ZN. The lack of discussion of the SGs presented also emerges from another study from 2021. Using the current dossier template, a total of only 23% of the evaluations submitted by the company were taken into account; on average, only 14% of the SG analyses presented by the company were even considered by IQWiG and/or the Federal Joint Committee in the assessment (Vfa, 2021). In general, IQWiG and the G-BA should justify the non-consideration of evaluations presented, as is done for excluded evaluations. All evaluations considered should be commented on in IQWiG's benefit assessment or the G-BA's decision, even if only in a concise form. Likewise, IQWiG and the Federal Joint Committee should provide constant commentary on results that are relevant to the evaluation and the conclusions.

In order to make decisions comprehensible and their appropriateness assessable, a discussion between the G-BA and IQWiG on the analyses individually required for each benefit assessment within the framework of a consultation appears to be a sensible approach. In general, the already existing consultation meetings could be used here to determine in advance the analyses to be submitted for the respective indication or product class in an exchange between all parties involved in the AMNOG benefit assessment. For example, a ‚core set' of central EPs defined by the G-BA - such as overall survival or SUE - would be conceivable for each assessment procedure. Only for these individually relevant EPs should SG analyses be mandatory, namely of prespecified and medically-biologically justified SGs. A blanket presentation of the subgroup analyses for UE according to SOC and PT should be completely dispensed with in view of the findings from this analysis. With regard to the endpoints on AEs, the evaluations of non-severe AEs can be dispensed with and overall a discussion is necessary on the adjustment of the boundary for the representation of any AEs according to SOC and PT. The corresponding adjustment of the dossier template and the exchange between IQWiG and the Federal Joint Committee with the company in advance in the context of a consultation appears to be more plausible and efficient than the current signal detection and offers the desired comprehensibility of the methodology for all parties involved.

Conclusion

The German benefit assessment procedure is considered a learning system. However, as the current AMNOG process is overall more inefficient than before the amendment of April 2020, a renewed adaptation of the dossier template is required. Only evaluations with actual added value for the benefit assessment should be mandatory. The obligation to present other evaluations, on the other hand, should be dropped. The evaluations on AEs and SGs relevant for the respective benefit dossier should be defined in advance and justified in order to ensure improved comprehensibility of the procedure of IQWiG and the G-BA. <<

by:
Dr. rer. nat. Maria Katharina Schweitzer[1] /
Dr. rer. nat. Manuel Nico Dold[2] /
Dr. rer. nat. Astrid Genet[3] /
Klaus Gossens PhD[4] /
Dipl.-Math. Thomas Klein-Hessling[5] /
Nils Löffler MSc[6] /
Dr. phil. Matthias Rabel[7] /
Dr. PH Andrej Rasch[8] /
Jessica Schmelcher MSc[9] /
Dr. rer. nat. Sebastian Werner[10] /
Natalia Wolfram[11]

1: Medical Writer, AMS Advanced Medical Services GmbH, München (ORCID: 0000-0002-9977-019X)
2: Medical Writer, AMS Advanced Medical Services GmbH, Mannheim (ORCID: 0000-0002-7272-2841)
3: HTA Manager, Pfizer Pharma GmbH (ORCID: 0000-0002-3781-1603)
4: Senior HTA Manager, AbbVie Deutschland GmbH & Co. KG (ORCID: 0000-0001-8508-7739)
5: Biostatistician, AMS Advanced Medical Services GmbH, München (ORCID: 0000-0003-2911-3220)
6: HTA Manager, Pfizer Pharma GmbH (ORCID: 0000-0001-9866-6756)
7: Biostatistician, AMS Advanced Medical Services GmbH, München (ORCID: 0000-0002-8161-9862)
8: Senior Manager Nutzenbewertung/HTA-Koordination, Vfa e. V. (ORCID: 0000-0003-4098-4502)
9: Medical Writer, AMS Advanced Medical Services GmbH, München (ORCID: 0000-0001-6435-9985)
10: Senior Manager Market Access/HTA, Vfa e. V. (ORCID: 0000-0002-8803-2589)
11: Lead HTA & Health Outcomes, AbbVie Deutschland GmbH & Co. KG (ORCID: 0000-0003-4951-219X)

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