# Balancing rigour and feasibility of real-world data demands in Germany within the EU HTA context – How fit for purpose is the routine practice data collection (Anwendungsbegleitende Datenerhebung, AbD)?

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## Background[1-4]

- Since 2019/2020, the Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA) has been empowered to initiate the application-related data collection (Anwendungsbegleitende Datenerhebung, AbD) procedures as part of the benefit assessment (Nutzenbewertung).[1-2]
- AbD applies to medicines newly authorised by the European Medicines Agency (EMA), where clinical evidence is limited (conditional approval, approval under exceptional circumstances, orphan drug designation).[2-4]
- Under the AbD procedure, manufacturers are required to collect data within a reasonable timeframe using existing or newly established, indication-specific patient registries. After the AbD period ends, the G-BA is expected to conduct a renewed benefit assessment of the product.[2-3]

## Objective & Methods

- The aim of this study was to evaluate the usability of AbD-data collection to identify critical success factors regarding implementation and their relevance in reassessments.
- A structured review was conducted of all AbD procedures published since 2020, including conceptual reports from the Institute for Quality and Efficiency in Health Care (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, IQWiG) and decisions by the G-BA.[5-6]
- The review focused on identifying barriers and enabling factors related to study design, operational implementation, and methodological acceptability.

## Results[5-6]

### Status of the AbD procedures

- By early August 2025, a total of 21 AbD procedures had been considered (**Figure 1**), with just two new initiations this year (belumosudil and lifileucel) reflecting the infrequency of such procedures.
- Overall, among the 21 procedures, data collection was mandated in 4 cases (~19%) and remains ongoing in 5 (~24%).
- One procedure was suspended following withdrawal of the EU marketing authorisation, requested by the manufacturer for commercial reasons (fidanacogen elaparvovec).
- In 2 requests (<10%), a decision was made not to proceed with data collection because the companies did not submit the study protocol and statistical analysis plan to the G-BA (talquetamab, fedratinib). In one of those cases, the decision emphasised expected difficulties in patient recruitment.

### The discontinued procedures

- To date, 7 of the 21 AbDs initiated were later stopped, representing one in three cases (**Figure 1**).
- The reasons fall into a few main categories: **legal constraints**, such as the absence of conditions required to mandate data collection (e.g., marstacimab); **insufficient feasibility of generating meaningful comparative data due to registry limitations** (e.g. iptacopan); and **significant challenges in patient recruitment**, either due to the structure of available registries (e.g. odronextamab) or the limited number of eligible cases within a reasonable timeframe (e.g. exagamglogen autotemcel).
- **In each case, the G-BA concluded that an AbD would not sufficiently improve the evidence base.**

### Key pitfalls and mitigation options

- The presented factors rarely act in isolation, underscoring the complexity of implementation (**Figure 2**). We identify **early stakeholder engagement and carefully planned, methodologically sound registry strategies as key enablers**. These findings point to actionable levers for strengthening AbD within the evolving EU HTA context.

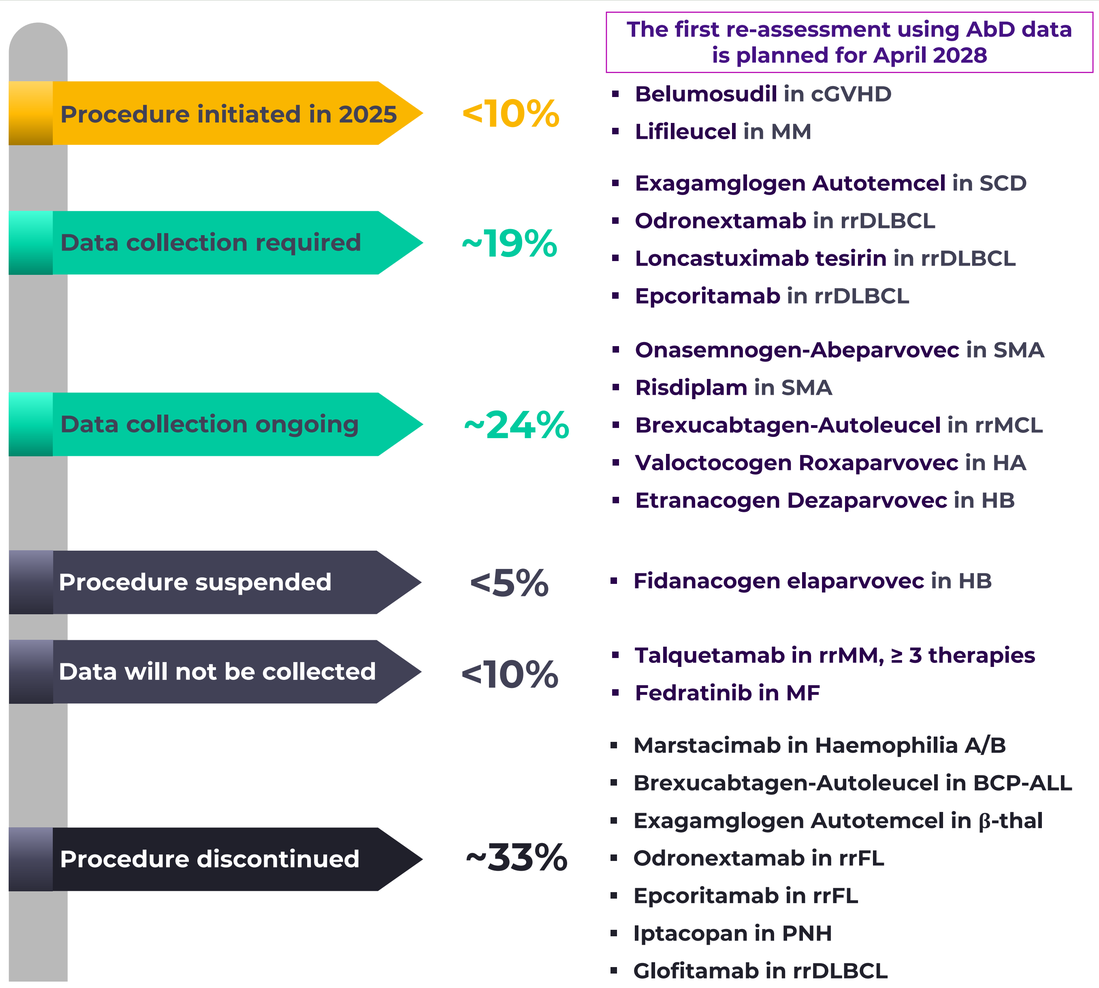
## Discussion

- The effectiveness of AbD hinges significantly on the quality and structure of supporting registries.
  - Registries with clearly aligned endpoints, transparent governance frameworks, and early, coordinated stakeholder involvement are more likely to generate data that meet the evidentiary requirements of IQWiG and the G-BA.
  - In contrast, attempts to retrofit existing registries often fall short, particularly when methodological standards, such as confounder control and data representativeness, are not met.
- Transforming AbD from a procedural formality into a meaningful HTA tool requires methodological alignment and early dialogue among regulators, manufacturers, and data custodians.
  - With the introduction of the EU HTA procedure, coordinated, pan-European registry strategies should be prioritised.
  - While this approach demands more upfront coordination, it allows for shared investment across countries and enhances the likelihood of generating high-quality, multi-country evidence suitable for joint assessments.

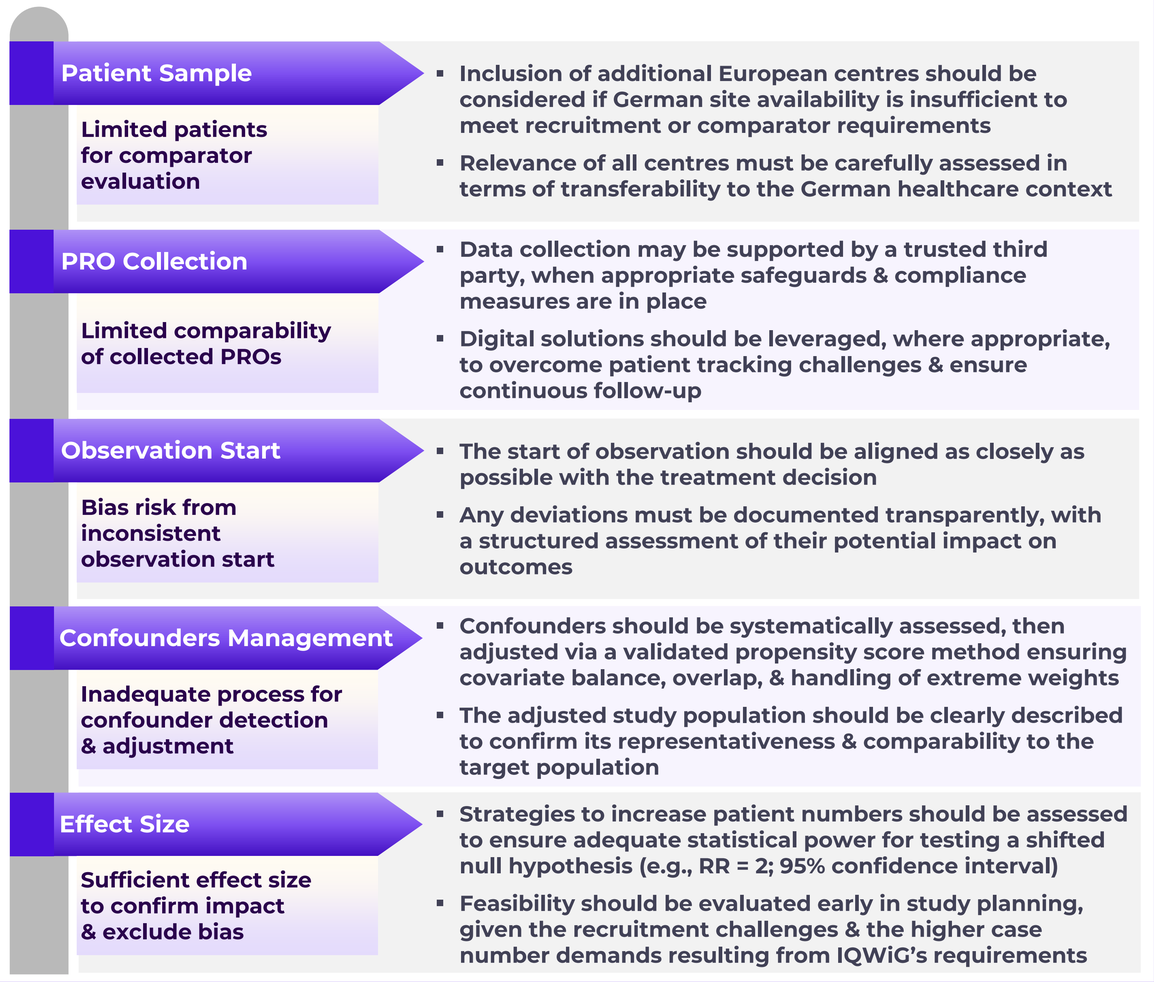
## Conclusions

- The AbD process remains underutilised due to recruitment challenges, operational barriers, and methodological limitations that affect data quality. No re-assessment has yet relied on AbD data.
- Early planning, stakeholder alignment, and coordinated registry strategies (particularly within the EU HTA framework) are essential for realising its full potential.

## Figure 1. AbD overview (as of August 2025)




## Figure 2. Key Pitfalls and Mitigation Options




### References

**1.** G-BA – Rules of Procedure https://www.g-ba.de/downloads/62-492-3830/VerfO_2024-10-17_iK_2025-05-29.pdf; **2.** G-BA – Medicinal Products Directive https://www.g-ba.de/themen/arzneimittel/arzneimittel-richtlinie-anlagen/; **3.** G-BA – Accompanying Data Collection under the Medicinal Products Directive https://www.g-ba.de/themen/arzneimittel/arzneimittel-richtlinie-anlagen/anwendungsbegleitende-datenerhebung/; **4.** IQWiG – General Methods (Draft Version 8.0) https://www.iqwig.de/methoden/allgemeine-methoden_entwurf-fuer-version-8-0.pdf; **5.** G-BA – Procedures for Accompanying Data Collection (AbD) https://www.g-ba.de/anwendungsbegleitende-datenerhebung-verfahren/; **6.** G-BA – Studies: Accompanying Data Collection (AbD) https://www.g-ba.de/studien/abd/

**Abbreviations**: AbD, Anwendungsbegleitende Datenerhebung; ALL, Acute lymphoblastic leukaemia; BCP-ALL, B-cell precursor acute lymphoblastic leukaemia; β-thal, Beta thalassaemia; cGVHD, Chronic graft-versus-host disease; DLBCL, Diffuse large B-cell lymphoma; EMA, European Medicines Agency; EU, European Union; G-BA, Gemeinsamer Bundesausschuss; HA/HB, Haemophilia A/B; HTA, Health Technology Assessment; IQWiG, Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen; MF, Myelofibrosis; MM, Unresectable or metastatic melanoma; PNH, Paroxysmal nocturnal haemoglobinuria; RR, Relative Risk; RWE, Real-World Evidence; rrDLBCL, Recurrent/refractory diffuse large B-cell lymphoma; rrFL, Recurrent/refractory follicular lymphoma; rrMCL, Recurrent/refractory mantle cell lymphoma; rrMM, Relapsed/refractory multiple myeloma; SCD, Sickle cell disease; SMA, Spinal muscular atrophy

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