SHL MEDICAL

Technical memo: Molly and MIDBA streamline mAb development programs

MIDBA overview and value proposition

In March 2026, the European Medicines Agency (EMA) published a qualified opinion regarding the Molecule-Independent Device Bridging Approach (MIDBA) [1]. MIDBA is designed to streamline the clinical development pathway for monoclonal antibodies (mAbs) from a pre-filled syringe (PFS) to an autoinjector offering. Under certain conditions, MIDBA allows the omission of dedicated pharmacokinetic (PK) comparability studies for each new therapeutic to establish bioequivalence between the PFS and autoinjector presentations.

Under MIDBA, existing PK and tolerability data from previously qualified molecules with similar physiochemical properties and using the same autoinjector platform can be used for new molecules, saving the need for additional bridging studies. As a result, MIDBA offers several practical benefits:

- Reduction in development timelines by eliminating PFS-to-autoinjector bridging studies.
- Lower clinical development costs through reuse of existing data.
- Portfolio-level efficiency, particularly for sponsors developing multiple molecules with shared characteristics.

These benefits position MIDBA as a mechanism to de-risk and accelerate device adoption within established biologics portfolios, rather than as a replacement for foundational clinical validation.

Molly specifications ensure MIDBA applicability

For the application of MIDBA, the following device prerequisites are stated in the EMA opinion: an exposed needle length of between 4 and 8 mm, an injection volume between 0.5 and 2 mL, and use of the same injection site(s) as the PFS presentation. These conditions are successfully satisfied by SHL Medical's Molly 1.0 and Molly 2.25 autoinjectors.

Device criterion	Prerequisite	Molly compatibility
Exposed needle length	4 – 8 mm	Yes
Delivered volume	Same as PFS; 0.5 – 2 mL	Yes
Injection site(s)	Same as PFS; abdomen, upper arm, or thigh	Yes

Table 1 – Device-specific criteria for MIDBA applicability to justify PK comparability between a PFS and autoinjector presentation of a mAb under consideration.

Regarding the drug product, additional criteria must be met for MIDBA applicability. The formulation and mAb must be the same between the PFS and autoinjector. With respect to absorption rate, the approach is intended for mAbs characterized by slow absorption into systemic circulation.

Molly is positioned within the design and use envelope supported by MIDBA, subject to the standard requirement that all relevant conditions (formulation, dosing, and clinical context) remain comparable.

SHL Medical's role in the establishment of MIDBA

MIDBA originated from an initiative led by F. Hoffmann-La Roche Ltd. (Roche) to reduce the need for repeated clinical bridging studies across mAb portfolios. This initiative was supported by a comprehensive review of comparative PK studies evaluating manual versus automated injection [2].

Importantly, the initial scientific concept put forward by Roche was device-agnostic, focusing on mechanistic and clinical comparability rather than any specific platform. Within this dataset, SHL Medical

played a significant role. Among the identifiable devices utilized in the studies, 12 out of 28 (43%) were designed and manufactured by SHL Medical, the largest contribution from any single device manufacturer.

SHL Medical's representation in the scientific foundation of MIDBA reflects a longstanding commitment to advancing self-injection solutions and facilitating the efficient development of innovative therapies.

Limitations of MIDBA

While MIDBA presents clear advantages, the qualification opinion contains limitations that constrain its application.

In terms of regulatory scope, the MIDBA qualification opinion is currently specific to the EMA, and applicability outside the European Union is not established.

The existence of a reference PK comparability dataset from reference mAbs is necessary for the approach. This dataset must include at least one product with similar physiochemical properties and which uses the same autoinjector platform as the mAb under consideration. This constraint may limit applicability of the approach in the clinical strategy of the first asset within a portfolio of mAbs. However, later assets may be able to reference the first mAb's PK comparability data to qualify for MIDBA if they are sufficiently similar.

The EMA explicitly notes that MIDBA is not a replacement for safety or tolerability assessments. Clinical data for safety and local injection-site tolerability are still required.

The EMA opinion is limited in scope to mAbs characterized by slow absorption rates into systemic circulation. The opinion states that this is to ensure that lymphatic uptake, rather than injection dynamics, is the primary driver of PK parameters. Other drug modalities with similar PK parameters and clinical development pathways do not fall within the MIDBA framework, such as peptides or fusion proteins.

Conclusions

MIDBA introduces a meaningful opportunity to reduce bridging studies and accelerate device-enabled therapies across biologics portfolios. Molly meets all key technical device parameters within the MIDBA framework and benefits from SHL Medical's strong representation in the underlying dataset.

Although it offers several advantages, MIDBA is limited by geographic scope, reference dataset requirements, and drug modality. Therefore, MIDBA should be regarded as a strategic tool within limits rather than a universal justification to eliminate the need for device bridging studies.

References

1. European Medicines Agency (EMA), *Qualification Opinion for Molecule-Independent Device Bridging Approach (MIDBA)*. March 20, 2026.
2. Bittner, B., et al., *Clinical Qualification of Subcutaneous Injection Devices for Monoclonal Antibodies.* BioDrugs, 2026. **40**(1): p. 5–21.