Your partner
in progress

BSI Breakthrough Device Pathway

Disruptive innovation.
Early market access.

Defining Breakthrough Devices (BtX)

A medical device or an in vitro diagnostic medical device is considered a breakthrough device if it meets each of the following criteria:

Novelty

The device introduces a high degree of novelty with respect to the device technology, the related clinical procedure, and/or the application of the device in clinical practice.

AND

Positive clinical impact

The device is expected to provide a significant positive clinical impact on patients or public health, for a life-threatening or irreversibly debilitating disease or condition.

For more information on the process and regulatory considerations relevant for qualifying, assessing and certifying breakthrough medical devices and IVDs see **MDCG 2025-9**.

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Supporting innovation

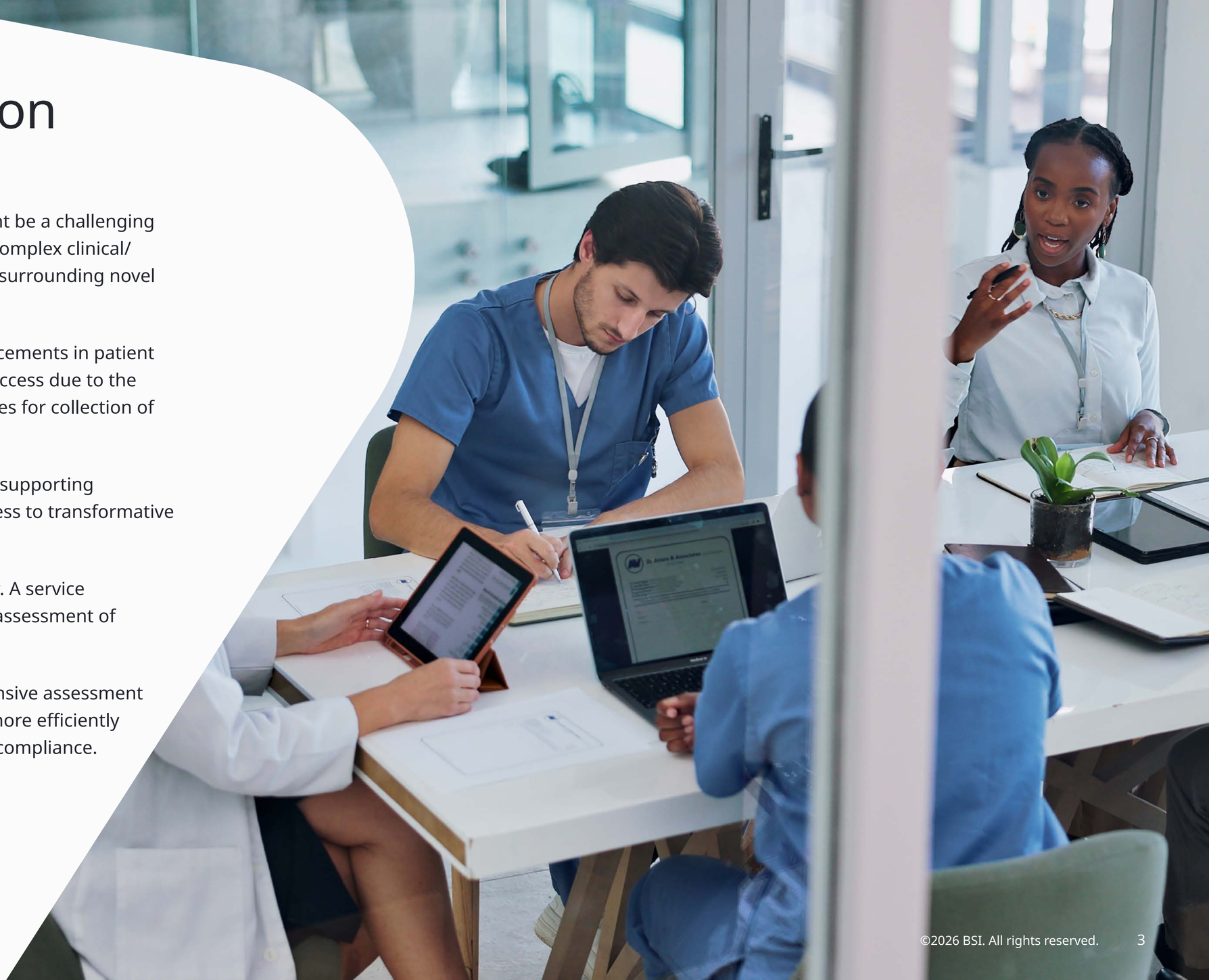
Bringing breakthrough medical devices to market might be a challenging process due to the rigorous regulatory requirements, complex clinical/ performance validations, and the inherent uncertainty surrounding novel technologies.

These devices, which often represent significant advancements in patient care, could experience delays in approval and market access due to the risks associated with such novel devices, the time it takes for collection of the required evidence, and the certification process.

BSI understands these challenges and is committed to supporting innovators and patients by enabling timely market access to transformative health technologies.

We have established the Breakthrough Device Pathway. A service specifically designed to support the timely conformity assessment of breakthrough medical technologies.

This dedicated route allows for a more agile and responsive assessment process, helping innovative devices reach the market more efficiently while maintaining the highest standards of safety and compliance.



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How does it work

BSI Breakthrough Device Pathway allows patients timely access to innovative technologies and devices addressing an unmet medical need.

This pathway is dedicated to devices that qualify as disruptive innovations offering new diagnostic or treatment options that do not currently exist in the EU.

You need to submit your device documentation to the EMA expert panel who will verify that your device meets the eligibility criteria as laid down in MDCG 2025-9.

Once your device is designated as a breakthrough device by the Expert Panels, the device can then be enrolled into the BSI BtX Pathway.

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Integrating BtX Pathway with Structured Dialogue

Combining the Breakthrough Devices (BtX) Pathway with BSI Structured Dialogue Service offers innovators a unique opportunity to engage early and proactively with BSI.

Manufacturers can benefit from consistent regulatory insight, timely clarification of clinical/performance expectations, and conformity assessment requirements, reducing uncertainty and development risk.

The integration of Structured Dialogue within the BSI BtX Pathway enables more efficient decision-making, optimized processes, and a smoother transition through the conformity assessment.

This combined BSI offering enhances predictability, supports innovation, and helps accelerate patient access to transformative medical technologies.

This dedicated route allows for a more agile and responsive assessment process, helping innovative devices reach the market more efficiently while maintaining the highest standards of safety and compliance.

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Breakthrough innovation meets Expertise

Eligible devices enrolled in the BSI BtX benefit from the BSI Dedicated Interactive Review Service **and gain priority in the review queue**. This review service is offered at **standard pricing**.

BSI Structured Dialogue

EMA Expert Panel BtX designation

Application to BSI

If you already have an application with BSI for a device which will subsequently meet BtX designation criteria, BSI will prioritize the conformity assessment for that device through the BtX Pathway Service.

Prioritized Conformity Assessment at standard pricing

Certification Issuance

BSI will consider to issue certification with conditions or provisions for those BtX for which the pre-market clinical evidence is deemed sufficient but needs to be completed or confirmed through PMCF/PMPF.

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Dedicated Interactive Review

Dedicated Interactive reviews foster flexibility, efficiency, predictability and transparency.

This review service consists of a remote technical documentation assessment which is performed interactively between manufacturers and reviewer(s) throughout the assessment to provide a collaborative, transparent and predictable service. The assessment dates, including any follow-up dates required to address open questions are planned and scheduled in agreement with the manufacturer.

This type of review is recommended to be delivered interactively to maximize all the benefits of the service. If the client chooses a less interactive review but still wishes to benefit from pre-scheduling and dedicated reviewer predictability, the review can be delivered fully remotely. There is no additional cost for a dedicated interactive review compared to a non-interactive dedicated review.

CE reviews eligible	All reviews, excluding PSUR and SSCP.
Scheduling of reviews	Pre-scheduled based on expected submission date.
Horizontal reviews	Run in parallel or scheduled to start in advance where external consultations are required.
Review coordination, opening and closing meeting	Integrated into the process. All manufacturer representatives encouraged to participate.
Manufacturer touchpoints	• Opening/closing meetings. Interactive review integrated into the process. • Real time dialogue during the initial review and after each formal round of questions. • Additional communication as per manufacturer or reviewer request.
Initial phase of the review	• Scheduled window of time (proportional to review duration). • Interactive chat /voice/video via MS Teams.
Rounds of questions	• Questions/clarifications any time during the initial review. • Formal questions, if needed, sent at the end of the initial review. • Maximum three rounds of questions.
Review question timing	• Response date aligned between manufacturer and reviewer recommended not to exceed 30 business days. • Responses reviewed once received without undue delay.

Note: Our services do not guarantee an EU certificate will be issued or that it will be issued within a certain number of working days but they are based on completing the review process with either a positive or negative recommendation. All type of reviews exclude time under consultation (e.g., Clinical Evaluation Consultation Process - CECP, devices utilizing animal tissue derivatives or medicinal substances which require Competent Authority involvement).

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Get in touch

Whether you are starting the certification process, looking to transfer or need to discuss your options, we can guide you through the process.

Talk to us

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