# Executive summary

Notified bodies (Team-NB and non-Team-NB members) have worked together since early summer 2025 to develop this proposal, outlining views on some of the most crucial topics. Six task forces were established covering:

* Early dialogue
* Article 61.10 & WET
* Digitalisation
* Coding for MD and IVD
* Designation and recertification
* Breakthrough

There are many other topics and areas of discussion which the notified bodies continue to engage with; this proposal is not an exhaustive representation of our interests in the ongoing MDR and IVDR review process. However, it is hoped that the views included in this proposal will be taken into consideration by the European Commission as part of the review process.

This document can be divided into five sections:

1. Executive summaries of each task force
2. Annex I: proposed legislative text amendments based on outputs from the six task forces
3. Annex II: proposed coding structure for medical devices and IVDs
4. Annex III: background information and written proposals for each task force
5. Annex IV: abbreviations

The notified bodies remain at the disposal of the European Commission if any further clarity or dialogue is required.

## Early Dialogue

An early dialogue system should be established to improve the transparency of the conformity assessment process. Early dialogue would allow manufacturers to gain an understanding of potential gaps prior to going through complete conformity assessment, increasing the overall speed to market. This would be beneficial for manufacturers, NBs and patients who will ultimately receive MDs faster.

The system must be built pragmatically, ensuring MDs still meet minimum thresholds on evidence. The proposal generated by NBs does not reduce the regulatory requirements for manufacturers but create a more open environment to discuss challenges upfront. This extends beyond the remits of current structured dialogue, venturing into the clinical domain.

Appropriate safeguards are important to maintain objectivity, independence, and impartiality, same as confidentiality and documentation of these discussions. The proposal includes a framework for the implementation of a general agreement between the parties involved.

## Article 61.10 & WET

The current MDR framework creates in some cases a contradiction by requiring clinical data for all medical devices, even when such data may not be appropriate. Article 61(10) was introduced to address this, but it has led to an artificial divide between devices with and without clinical data, which does not reflect real-world practice.

This divide leads to lengthy debates between manufacturers and notified bodies whether Article 61.10 is applicable or not, rather than focusing on the best evidence to demonstrate safety, clinical benefit and performance. In reality, most devices rely on a mix of clinical and non-clinical data, and the required balance varies by device.

Our proposal aims to:

* Redefine the criteria for the applicability to narrow the scope of Article 61(10) and clarify its application.
* Broaden the definition of clinical data (Article 2(48)) to include real-world evidence, post-market data, and relevant international sources.
* Redefine clinical evaluation (Article 2(44)) and clinical evidence (Article 2(51)) to include clinically relevant non-clinical data.
* Clarify that clinical evaluations are typically based on clinical data but may incorporate other relevant data.
* Issue MDCG guidance to reflect a more holistic understanding of “sufficient clinical evidence.”

**Expected Impact:**

* Reduces the artificial barrier between clinical and non-clinical data.
* Aligns regulation with reality, improving clarity and efficiency.
* No additional burden or costs are expected, as it is adding solutions for devices which are currently struggling to obtain a certificate

## Digitalisation

Digitalisation offers significant potential to improve regulatory efficiency and reduce costs. Under MDR and IVDR, enabling fully digital processes—such as machine-readable documentation and remote audits—can streamline assessments by notified bodies. In the future, intelligent assistant systems may support data-driven instead of document-driven product evaluations.

Advances in computing and AI also support the use of in silico methods (e.g. simulations) to generate evidence of device safety and performance. These methods can contribute to the 3Rs—replacement, reduction, and refinement—of animal testing.

Our proposals aim to:

* Enable digital regulatory processes.
* Recognise in silico methodologies as valid evidence sources.

## Coding for MD and IVD

NBs have produced a proposal to amend the existing coding structure for MDs and IVDs. This can be found in [Annex II](#_Annex_II:_Proposed).

Consolidating and eliminating codes will have a measurable but manageable impact on devices currently placed on the EU market under the IVDR by reducing complexity and aligning practices. Competence within NBs would be maintained, while these positive impacts would be recognised through streamlined processes across multiple stakeholders.

These proposals should be implemented in a pragmatic way with robust guidance and support to ensure consistency and minimisation of difficulties.

Impact

* Labelling and Documentation: No impact to device performance or intended use (change is administrative, no effect on device safety, clinical purpose, or analytical functionality); updates to technical documentation may be required to align with the new IVR code, particularly SSP, Declarations of Conformity, or risk classifications; device labelling is unlikely to require changes.
* NB Certificates and Surveillance: Certificates issued may need to be updated or reissued; no immediate re-certification is required solely due to the code consolidation; surveillance activities should reference the updated IVDR code going forward, with clear documentation of equivalence to the legacy code(s); effect on sampling plans.
* Transitional Considerations: Defined transition required (e.g., until renewal), during which: both legacy and new codes are accepted in regulatory submissions and NB scope documentation AND manufacturers may reference both codes in parallel; guidance and communication is required across stakeholders to ensure consistent implementation with clear equivalence.
* No recall or withdrawal of devices from the market is necessary as the change does not affect conformity status or legal placement.

## Designation and reassessment

* Designation process should be streamlined and shortened.
  + The designation process should be centrally governed to avoid time-consuming exchange of information between the involved CA/DAs and the applying NB.
  + The formal communication timelines (e.g. Nando publication timeline), including the number of communication steps, should be simplified.
  + Faster designation process would reduce advance financial investment by NBs.
* Scope extensions of already designated NBs (MDR Art. 46, IVDR Art. 42) should not follow the same process as the initial designation process but focus on the scope extension.
* In case of cessation of NB activities, a controlled transfer of certificates is needed avoiding the obligation of full reassessment.
* Clear expectations regarding Rules and review of Qualification criteria should be defined (MDR/IVDR Annex VII, NBOG 2017-2, MDCG 2019-6 Rev5).

## Breakthrough

A coordinated pathway should be established for products deemed to be “breakthrough”, i.e. novel devices with a clear clinical need for patients or the healthcare system. Although such devices are relatively few, they have the potential to add a significant benefit to patient management and public health. For such devices, it is typically challenging to generate robust clinical evidence due to a multitude of factors. This must be taken into consideration within this new pathway to ensure the products entering the EU market remain safe and effective, while allowing an achievable volume of supporting evidence.

NBs propose a system that involves a breakthrough designation granted by the European Commission or expert panels. This designation would allow NBs to utilise conditional certificates with defined post-market expectations for manufacturers to gather additional evidence where required. Clear guidance and oversight of the system is essential.