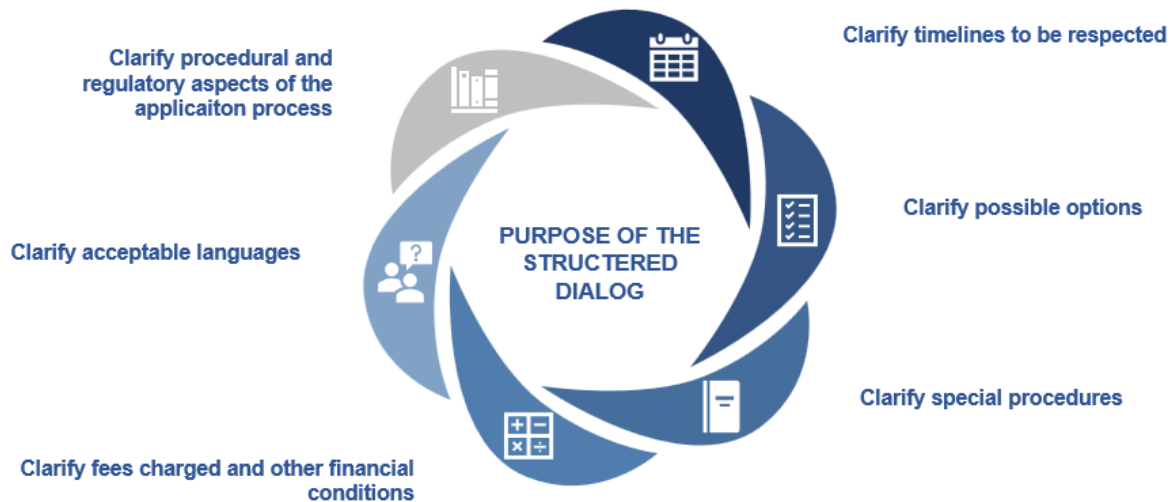


The purpose of a structured dialogue prior to submitting a formal MDR application with NOTICE (pre-application) is to clarify the timing, procedural, and regulatory aspects of the application process, including the required forms & submission documents and any other related aspects.

The structured dialogue can also be conducted during the conformity assessment process (i.e. post-application).



\* These structured dialogues are independent of the assessment process and are focused on “what needs to be fulfilled” rather than “how to fulfil”.

The following items can be discussed during the structured dialogue:





## Administrative questions

### Pre- application

- Timelines for conformity assessment until certification, including estimated timelines for possible special procedures.
- Clarification on the data / documentation to be provided with the application.
- Options of conformity assessment procedures and timing for submission of individual technical documentation.
- Information on all necessary conformity assessment activities.
- Pricing and fees
- Exchange of information about involved persons for different conformity assessment activities on both sites.

### Post-application

- Clarification of missing data.
- If test reports were initially not accepted, the next steps regarding the submission of new test data.
- Timelines for providing additional missing data.
- Early information / discussion on a planned significant / substantial change of a product (design) and the consequences for the certification process.



## Regulatory guidance / requirements

### Pre- application



- Applicable standards and guidance documents.
- How to apply and reference standards or guidelines.
- Referring to the possibility of getting advice by EMA expert panels (Art. 106, Art. 61 (2) MDR)
- Possibility of “modular approach”.
- General requirements regarding and acceptance of (third party) test reports / certificate.
- Leveraging evidence from previous assessment.

### Post-application



- Leveraging evidence from previous assessment.
- Appropriateness of equivalence claim (see Art. 61(4), second indent, MDR.
- Sufficiency of quality / quantity of clinical data.
- Applicability of Article 61(10) MDR.
- Appropriateness of PMCF plan.



## Technical information

### Pre- application



- Qualification and Classification of a product (Annex VII 4.2 (d) MDR).
- Requirements for sampling of devices for technical documentation assessments.
- Best practice guidance for TD, including preferred structure of TD.

### Post-application



- Clarification of non-conformities raised.

## Structured Dialogue Process

To request a Structured Dialogue meeting, please email [info@notice.si](mailto:info@notice.si).



A mutually convenient date will be arranged between you and the relevant NOTICE experts.



Please specify any particular topics you wish to discuss during the meeting.



NOTICE will finalize the agenda and send it back to you.



You need to provide all required documents requested by NOTICE experts at least one week before the meeting date.



The agenda will be covered during the meeting.



NOTICE will inform you of the next steps.



### **Contact Information**

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