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Questions & Answers - Practical arrangements on the companion diagnostics consultation procedure to the European Medicines Agency by notified bodies

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1. How and when should I submit "a letter of intent" for an initial consultation procedure on a companion diagnostic? Rev. April 2026

Please notify the Agency of the intention to submit an application for an initial consultation on companion diagnostic by sending "a letter of intent" at least three months in advance of the expected date of submission.

Please send "the letter of intent" by raising a ticket via EMA Service Desk, selecting the tab "Business Services", category "Human Regulatory". The subcategory to be selected is "Pre-Submission Phase - Human", followed by the sub-option: "Companion Diagnostics Request". Please do not send any documents to individual email addresses within the Agency.

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If you do not have an EMA Account, please create it via the EMA Account Management portal. For further information or guidance about how to create an EMA Account reference the guidance "Create an EMA Account".

The template for the intention-to-submit letter can be found on the EMA webpage on CDx.

Also, since the medical device manufacturer is responsible for paying the fees for this consultation directly to the EMA, they should ensure that a customer account number is requested via the Agency's Accounts Receivable service (accountsreceivable@ema.europa.eu) sufficiently in advance of the intended submission deadline. The request to create the customer account number should be linked to the timing of the letter of intent submission, and the account number should be included with the submission.

2. How should I notify a change in the contact person and/or intended submission date of my application?

In case the previously indicated person of contact and/or the submission date of an upcoming consultation is changed, the applicant shall inform the EMA by raising a ticket via EMA Service Desk, selecting the tab "Business Services", category "Human Regulatory". The subcategory to be selected is "Pre-Submission Phase - Human", followed by the sub-option: "Notification of Change Request".
If you do not have an EMA Account, please create it via the EMA Account Management portal. For further information or guidance about how to create an EMA Account reference the guidance "Create an EMA Account".

3. How and when is the Rapporteur appointed?

Following receipt of "the letter of intent", the Agency will trigger the appointment of a Rapporteur by CHMP and CAT. The applicant will be informed of the outcome.

4. Who is my contact at EMA during a companion diagnostic consultation procedure?

In the context of a companion diagnostic consultation procedure to the EMA, the Product Lead (PL) is the primary contact for the applicant prior to submission and throughout the procedure until the Scientific Opinion by the Committee for Medicinal Products for Human Use (CHMP).

The notified body will be notified of the allocated PL after the submission of the letter of intent, together with the allocation of the EMA product number.

The PL will serve as the main liaison person between the Rapporteurs and the applicant. The PL will ensure that the applicant is kept informed of all aspects related to the MAA evaluation.

The applicant should contact the PL for all questions regarding the consultation procedure, including:

- Questions concerning the validation of the consultation procedure;
- Requests for guidance in the pre-submission phase, such as the pre-submission interactions;
- Any type of procedural questions during the evaluation, such as availability of assessment reports and Opinion documents;
- Discussion on timetables;
- Any question where guidance related to the evaluation procedure is needed.

5. How can I request pre-submission interactions with the Rapporteurs?

The EMA recommends early interactions between the relevant notified body, the device manufacturer, and the marketing authorisation holder(s) or applicant(s) of the medicinal product(s) (as applicable and relevant). Questions concerning timing, regulatory or procedural aspects of the CDx consultation can be sent by the notified body to the appointed product lead after receipt of the intention to submit-letter and within 2 months of the planned submission. These questions will be answered in writing by the EMA in due time. If additional guidance is needed, the notified body can request a pre-submission meeting with the product lead, the rapporteur, the device manufacturer and marketing authorisation holder(s)/applicant(s) of the medicinal product(s) (as applicable and relevant).

6. How and when should I submit an application for an initial consultation procedure on a companion diagnostic?

The eSubmission Gateway and the eSubmission Web Client are mandatory submission channels for the submission of applications to EMA (including Supplementary information requested during validation).

The eSubmission Gateway and the eSubmission Web Client are electronic submission channels that allow the applicants to submit documents supporting all types of applications to the Agency securely over the internet in structured and non-structured formats.

Links and detailed information on the systems required:

1. eSubmission Gateway Web Client and eSubmission Gateway web client: Guidance for applicants.
2. xml Delivery File and Guidance for submissions using xml delivery files (refer to section *4.8. Create delivery file for Medical Devices*).

Information on how to register to eSubmission Gateway and detailed guidance for all submission types can be found on the eSubmission website. The registration on eSubmission Gateway and the eSubmission Web Client should been done sufficiently in advance of the intended submission deadline as it can take up to 20 days for the application registration to be completed.

All submissions sent to EMA via eSubmission Gateway/Web Client will be considered delivered to all National Competent Authorities representatives, alternates and experts of the scientific committees.

There should be no additional copies of submissions sent directly to the NCAs on CD/DVD or via CESP as this might lead to validation issues and cause delays. All EMA submissions should be sent via EMA eSubmission Gateway/Web Client only.

For technical issues with the submissions visit the EMA Service Desk portal.

Specific timetables for companion diagnostics are published on the EMA webpage.

In order to facilitate the registration of the submission, applicants are required to fill in all the submission attributes through the eSubmission delivery file.

The Notified Body is advised to submit the application for the companion diagnostic consultation procedure during the last phase of the evaluation of the Marketing Authorisation Application of the medicinal product associated with. The Notified Body and device manufacturer are advised to liaise closely with applicant / MAH of the medicinal product to be informed about the medicines evaluation phase, in particular, when approaching opinion stage.

7. What fee do I have to pay for consultation procedure on companion diagnostics? Rev. April 2026

For information on fees to be paid, applicable fee reductions and payment process, please refer to the Fee Q&As in Annex IV, Section 7.3, on the Fees payable to the European Medicines Agency page.

As envisaged in said Rules and Explanatory note, although the notified body requests the consultation from the EMA, the medical device manufacturer is responsible to pay the fees for this consultation directly to EMA.

A customer account number should be requested by the medical device manufacturer via the Agency's accounts receivable service at accountsreceivable@ema.europa.eu sufficiently in advance of the intended submission deadline, ideally at the time of the Letter of Intent submission (please see the first question above) and provided with the submission.

Fee reductions are applicable for scientific services (e.g. consultation procedure) for medical device manufacturers with SME status as registered at the European Medicines Agency SME office. For more information, please refer to the 'SME user guide for micro, small and medium–sized enterprises'.