

# Advice BAREC patient facing documents

This advice by BAREC was endorsed by the College Board during the meeting of 24/01/2025.

Based on the Question & Answers document provided from the Clinical Trials Regulation (EU) No 536/2014, not all patient facing documents need to be submitted for EC review.

Patient facing documents are defined as documents, other than recruitment material or subject information sheets, presented to clinical trial participants during the conduct of the clinical trial.

Patient facing documents that are linked to the endpoints of the clinical trial shall be provided together with the protocol in part I of the clinical trial application, in the same language as the submitted Informed Consent Forms (ICFs) . These documents will be assessed during the part I assessment.

Other patient facing documents, other than documents that are linked to the endpoints of the clinical trial, should be submitted in Part II. Any document that might influence the decision of a participant to take part in the study should be submitted for EC review to ensure compliance with ethical and transparency standards.

Here's a list of patient-facing documents that sponsors are **not required** to submit (no EC review necessary):

- Insurance certificate in language of the patient
- Patient cards, trial identification cards
- Instructions on how to use a tablet or phone to complete e.g. e-questionnaires
- Digital vouchers/cards used to reimburse participants
- Welcome Letter
- Thank you card
- Dosing diaries
- Letter to ask participants to fill in their diary
- Retention items (calendars, water bottles, and similar items). However, if these materials are provided as compensation or a form of incentive, this must be clearly disclosed as part of the submission. Those items should not include prominent or large advertisements for the study.
- Travel Policy: Outlines guidelines for pre-paid travel services and reimbursements
- Pay Portal Guide: A guide on how to set up a portal to receive payments
- ...

*Note:* These are examples. Sponsors are responsible for determining if a specific document falls within this category.