December 2025

Newsletter

Table of contents

1. BAREC statement about the collection of ethnicity data in clinical trials

BAREC has updated its advice regarding the collection of ethnicity data in clinical trials: https://barec.be/barec-statement-for-the-sponsors-and-ecs-on-the-collection-of-ethnicity-data-in-clinical-trials/. The earlier version stated that *race* could also be collected — this term has now been removed and is now in line with the ICF template. The updated advice focuses exclusively on ethnicity data.

The revised statement highlights the importance of having a diverse and representative study population, ensuring that research outcomes are relevant to society as a whole. Accurate and careful reporting of ethnicity can help improve understanding of cultural, social, and biological differences, and support the identification of population groups that may be disproportionately affected by certain diseases.

BAREC states that when researchers consider collecting ethnicity data, they should:

- provide a **clear scientific justification** in the protocol and informed consent form (ICF);
- comply with **GDPR principles** and ensure appropriate safeguards for participant privacy;
- clearly inform participants about the voluntary nature of sharing such sensitive information. It is crucial to ensure that individuals have the freedom to decide whether they wish to share such information;
- and include measures to **prevent or address discrimination**.

If an Anglo-Saxon sponsor chooses to use the term *race* in the study protocol, BAREC does not consider it necessary to systematically request changes to this terminology, as long as it is applied respectfully and within the applicable legal and ethical frameworks. The term "*race*" should however not be used in any patient facing documents. BAREC expects EC's to critically assess its appropriateness within the specific study context.

2. Fast-Tracking Clinical Trials

Fast-track mononational clinical trials

In recent weeks, representatives of BAREC, the College, and the FAMHP have met to discuss ways to accelerate the assessment of CTR-studies in Belgium.

From 1 January 2026, accelerated timelines for the evaluation of **mononational** initial applications for clinical trials with medicinal products for human use will be implemented. This measure will allow clinical research to start more quickly, ultimately benefiting patients and strengthening Belgium's leading position as a hub for clinical trials.

One of the key outcomes of these discussions is that the timelines related to the College's evaluation are now clearly defined and transparent. The period allocated to the College will consistently be maximum three days, ensuring predictability and efficiency in the overall assessment process.

You can find more details in the official communication published on the FAMHP website:

- FAGG versnelt beoordeling van klinische proeven om innovatieve behandelingen sneller tot bij de patiënt te brengen | FAGG
- L'AFMPS accélère l'évaluation des essais cliniques pour permettre un accès plus rapide aux traitements innovants | AFMPS

Fast-track multinational clinical trials

National Competent Authorities (NCAs) and Ethics Committees across Europe also announced their commitment to pilot a **coordinated fast-track approach** for the evaluation and authorisation of multinational clinical trials. This initiative, known as **FAST-EU (Facilitating and Accelerating Strategic Trials)**, represents a significant step in strengthening Europe's position in clinical research.

FAST-EU is aligned with the European Commission's forthcoming legislative efforts to streamline procedures for **multi-country trials**. The approach introduces **clear timelines and coordination mechanisms**, aiming to provide sponsors with greater predictability, reinforce confidence in the European regulatory framework, and attract research investment—while upholding scientific, safety, and ethical standards.

The pilot is scheduled to begin in **January 2026**.

Importantly, Ethics Committees' opinions from all participating Member States will be integrated into this ambitious process, setting Europe apart from other regions.

You can find more details in the official communication published on the EMA website: https://www.hma.eu/about-hma/recently-published.html

3. Guide on human body material for research use

BAREC is pleased to announce the release of the **Guide on Human Body Material for Research Use**. This decision tree provides insights and practical guidance for researchers working with human biological materials, ensuring ethical and compliant practices across all stages of research.

The decision tree describes definitions and the scope of human body material in research and step-by-step guidance on consent procedures and ethical approvals.

For the full advice, we refer you to the BAREC website: https://barec.be/guide-on-human-body-material-for-research-use/

BAREC is also developing an **interactive tool** that will allow users to easily navigate through the decision tree and quickly find the information they need.

4. Harmonisation of fees

To promote transparency and consistency, BAREC has harmonized several fees that are not legally mandated but are essential to support the administrative processes of Ethics Committees.

Based on feedback from its members, the BAREC Board has approved the following updated amounts:

Category	Description	Fee (EUR)
Biobank Recognition	Initial recognition fee and bi-annual reassessment fee	**€ 2000**
Retrospective Commercial Studies	Initial fee	**€ 656.76**
	Amendment fee	**€ 164.21**
Commercial studies on secondary use of Human Body Material (HBM)	Same rates as retrospective commercial studies	
Non-Study-Specific Recruitment Materials	Review fee	**€ 500**

You can consult the full advice on the BAREC website: https://barec.be/harmonisation-of-fees/

5. BAREC Advice for hospital sites on involvement of local EC

BAREC has taken note of the letter from the College, dated 1 December 2023, concerning the internal "green light" procedures implemented by some hospital institutions through their local ECs in CTR-studies. In response, BAREC wishes to share its position and recommendations on this matter.

According to Article 70 of the Law of 10 July 2008 on hospitals and other healthcare institutions, every hospital must have a local ethics committee. This committee should be responsible for:

1. Providing ethical guidance and advice on hospital care; and
2. Offering opinions on protocols related to experiments involving humans or human reproductive material.

BAREC understands that institutions aim to comply with this legal requirement and acknowledges their intention to keep local ECs informed about ongoing or planned clinical studies. However, BAREC wishes to underline that the current legal framework — namely the Clinical Trial Regulation (CTR, EU No. 536/2014) and the Law of 7 May 2017 on Clinical Trials with Medicinal Products for Human Use — stipulates that the ethical evaluation of clinical trials in Belgium is the exclusive responsibility of an independent ethics committee.

BAREC also shares the College's concern that internal institutional procedures should never delay the actual evaluation or initiation of a clinical trial.

Accordingly, BAREC provides the following recommendations to Belgian ECs and hospital institutions:

- If an institution chooses to maintain or introduce an internal "green light" procedure, it must ensure that this process does not cause any delay in the conduct of the clinical trial.
- Local information or consultation moments can be useful but should take place in parallel with or prior to the formal submission — not as an additional requirement after a positive opinion and approval have been granted.

You can consult the full advice on the BAREC website: https://barec.be/advice-for-hospital-sites_on_involvement-of-local-ec/

6. BAREC Symposium: “The role of Ethics in research”

The next BAREC Symposium is scheduled to take place on **28 March 2026**. This edition will once again be organized jointly with the College, continuing the successful collaboration of previous year.

Further details regarding the program and registration will soon be shared. We look forward to welcoming you to another inspiring and engaging symposium!

7. Follow-up pregnant participant/partner in an interventional clinical trial

BAREC has issued an advice regarding the follow-up of a pregnant participant and a pregnant partner in an interventional clinical trial.

For the full advice, we refer you to the BAREC website: https://barec.be/qa-pregnancy-follow-up/

In clinical trials involving medicinal products, monitoring pregnant participants and pregnant partners is essential to assess potential teratogenic or embryotoxic/foetotoxic effects.

Pregnant participants

- Monitoring is subject to **pharmacovigilance** and requires reporting all adverse events including those during pregnancy.
- An ICF for follow-up of the **child** is required, this can be part of the main ICF or created separately, preferably with two signatures.

Pregnant partners:

- Follow-up is considered a separate observational study, with details specified in the clinical trial protocol, including the follow-up duration.
- A detailed ICF for the partner and child is mandatory and must include an insurance clause.
- If additional procedures are involved (e.g., questionnaires or phone calls), it becomes an interventional study, necessitating a separate ICF.

The duration of follow-up depends on factors such as the drug's half-life and evidence of long-term effects.

8. New Publication – Audrey Van Scharen

BAREC member **Audrey Van Scharen** recently published the article *“Ethics Review or Compliance Check? An Empirical Analysis of 6,740 Requests for Information in Belgian Clinical Trial Evaluations (2017–2024)”* in **BMC Medical Ethics**.

The paper provides the first large-scale empirical insight into how Belgian ethics committees operate under the EU Clinical Trials Regulation (CTR), analyzing the balance between ethical reflection and regulatory compliance. It concludes with recommendations to strengthen both the efficiency and quality of ethics review in Belgium and beyond.

Read the article here: https://link.springer.com/article/10.1186/s12910-025-01296-0

9. Retention periods for study documents in clinical research

A new BAREC advice provides a clear overview of the retention periods that apply to study documents in clinical research, based on current European and Belgian legislation.

Retention periods differ depending on the type of study and the applicable regulation:

Study type or applicable law	Information about retention period
GDPR	No longer than is necessary for the purposes for which the personal data are processed
CTR	At least 25 years after the end of the clinical trial.
MDR	- for a period of at least 10 years after the clinical investigation with the device in question has ended - for a period of at least 10 years after the last device has been placed on the market. - Implantable devices: at least 15 years.
IVDR	- for a period of at least 10 years after the clinical investigation with the device in question has ended - for a period of at least 10 years after the last device has been placed on the market.
Experiments	No legally defined retention period. Sponsors must determine an appropriate minimum duration, justified in the study documents (e.g., protocol or informed consent form). When setting this period, sponsors are encouraged to consider GDPR compliance, cost-efficiency, and environmental sustainability.

For the full advice, we refer you to the BAREC website: https://barec.be/advice-from-barec-regarding-the-retention-periods-for-study-documents-in-clinical-research/

10. Informed consent and lifting of traceability of samples

When biological samples are anonymized, their traceability to the donor is permanently lost. This has significant legal and ethical implications, as donors waive several rights, including:

- **The lifting of traceability of samples collected from living donors is subject to the condition of obtaining the donor's consent** (HBM Law, Art. 2 and 23)
- **The right to receive meaningful information** resulting from analyses (HBM Law, Art. 22)
- **The determination right** regarding the use of their samples (Belgian Advisory Committee on Bioethics, Advice No. 45)

Under the Law of December 19, 2008 on Human Biological Material (HBM Law), lifting traceability requires explicit prior consent from the donor. If consent cannot be obtained, a fully accredited ethics committee must provide a positive opinion. These principles are reinforced by the Law of August 22, 2002 on Patients' Rights, which guarantees the right to be informed about health-related information.

The above motivation can be used when responding to questions from external parties or sponsors on this matter.

Implications for the Informed Consent Form (ICF):

- The ICF must clearly explain what lifting traceability means and its consequences.
- Donors should be informed that anonymization results in the loss of rights mentioned above.
- The consent process must ensure donors understand their options and legal implications.
- Sponsors must maintain systems to record whether consent for lifting traceability has been granted.

Although the HBM Law excludes clinical research from its scope (Art. 3, §3(f)), these principles apply *mutatis mutandis* to clinical trials and prospective research. Therefore, prior consent for anonymization should always be documented in the ICF.

For the full advice, we refer you to the BAREC website: https://barec.be/lifting-of-traceability-of-samples-hbm/

11. Symposium on Drug Development: From Bench to Bedside

We are delighted to announce that our Board member, Audrey Van Scharen, will join the *2026 Symposium on Drug Development: From Bench to Bedside* as an invited speaker.

Her lecture about Decentralised Clinical Trials will take place on Friday, 24 April 2026, from 13:55 to 14:15 at Zebrastraat, Ghent.

Don't miss this opportunity to engage in an interactive discussion on the future of clinical research.

Register now: https://www.eventbrite.be/e/2026-symposium-drug-development-from-bench-to-bedside-registration-1628500812769

12. BAREC Membership

We kindly invite you to join BAREC or renew your membership for 2026. The fee for the ECs recognized under the law of 7 May 2017, remains 450 euro and 300 euro for the other ECs.

Please make a payment to the following bank account number: BE35 0689 3066 7537

Should your hospital/EC require an invoice to perform the payment, please let us know.

We look forward to having you all on board again in 2026!