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EU HTA Joint Scientific Consultation: 2026 Workflow Guide

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Executive Summary

The European Union (EU) Health Technology Assessment Regulation (HTAR) lets developers of medicines, high-risk medical devices and class D in vitro diagnostics (IVDs) obtain a joint scientific consultation (JSC) while clinical studies are still being planned, so that the later evidence package can meet the likely needs of a joint clinical assessment (JCA). The outcome carries no legal effect and cannot prejudice a later JCA (eur-lex.europa.eu). As of 29 November 2026, the JSC is free of fees for the HTA Coordination Group (HTACG) route.

The calendar is the main operational constraint. Requests can only be submitted in published request periods (health.ec.europa.eu), and the final 2026 period ran from 23 September to 21 October 2026, so it has already closed. It offered three slots: briefing documents due 11 January, 8 February or 15 March 2027, with discussion meetings from the weeks of 12 April, 10 May and 7 June 2027 (hadea.ec.europa.eu). The HTACG planned to approve its 2027 work programme by 30 November 2026 (health.ec.europa.eu), and the implementing rules require at least three request periods a year. The Commission JSC page listed no 2027 request dates when this guide was last checked (29 November 2026), so teams should treat them as unconfirmed and recheck that page.

Route choice is the first decision. An HTACG-only JSC and a parallel HTACG/European Medicines Agency (EMA) JSC each take approximately 4.5 months for medicines (health.ec.europa.eu). For devices, the parallel route involves the EMA-hosted expert panels and is not available for IVDs (health.ec.europa.eu). Capacity is limited: the 2026 programme planned 8 to 12 medicine JSCs and 2 to 5 device JSCs (health.ec.europa.eu), and by June 2026 the Commission reported 7 JSCs started in 2025, all completed, plus 7 started in 2026, two of them parallel.

The intake workflow is short but strict. A developer emails the HTA secretariat with an EU Login username, without commercially sensitive content, and then receives an access link to the HTA IT Platform (health.ec.europa.eu). Platform access can take a few days. All product-specific exchange then happens on the platform. Questions should be organised by population, intervention, comparator and outcome (PICO), because the JSC covers comparators, interventions, outcomes and populations (eur-lex.europa.eu), and the medicines template recommends at most 10 questions (health.ec.europa.eu). Selection is not guaranteed: when requests exceed planned slots, the Coordination Group applies six criteria (eur-lex.europa.eu). Nothing in this guide implies selection, regulatory acceptance or commercial benefit.

Introduction and Background

Regulation (EU) 2021/2282 created a framework for joint work on health technology assessment (HTA) at EU level, including JSCs. A JSC is distinct from the JCA: it happens before pivotal studies, whereas the JCA happens around marketing authorisation. The JSC is meant to advise on study or investigation design, including comparators, interventions, health outcomes and patient populations. Eligibility requires that the clinical studies are still in the planning stage (eur-lex.europa.eu).

This guide is written for market-access, clinical-development, health economics and outcomes research (HEOR) and regulatory-operations leads. It turns the official documents into an intake-to-meeting workflow. It is not a JCA dossier overview. IntuitionLabs is a life-sciences and AI consultancy and a Veeva X-Pages Partner; it writes here as an adjacent advisor and not as a software vendor or a provider of HTA services; nothing below is a vendor comparison.

A note on timing. The final 2026 request period was open from 23 September to 21 October 2026 (hadea.ec.europa.eu). At the publication date of 29 November 2026 it has closed, so the practical decisions are: (a) which of the three slots allocated from that period to plan around, if a request was filed; and (b) how to prepare for the 2027 cycle. The Commission's JSC page still lists the 2026 periods and the slot table as of this writing. The device template PDF carries a "June 2026" date, while the Commission landing page shows no date for the Word file, so the version should be confirmed by logging the file name and download date. The published meeting weeks start 12 April, 10 May and 7 June 2027, so they run from April to June.

The institutional record is short. Smaller companies are a specific concern: industry groups said that discussing evidence generation plans with assessors is particularly important for small and mid-sized firms (www.raps.org). The 2026 work programme was adopted by the HTACG on 28 November 2025 (health.ec.europa.eu). A Drug Information Association (DIA) Global Forum review of the first six months noted that the transition "remains challenging" (globalforum.diaglobal.org). The predecessor, EUnetHTA Joint Action 3, received 113 pharmaceutical early-dialogue requests between June 2017 and May 2021 and conducted 38 (www.cambridge.org). That ratio helps explain why industry associations called for more slots before 2025: they noted the Coordination Group had scheduled only 5 to 7 meetings (www.raps.org), while a subgroup survey identified over 50 products likely to request advice (www.raps.org). Those meetings focus on the design of clinical trials and plans for evidence generation (www.raps.org).

Eligibility and Selection: Who Can Ask, and Who Is Selected

Medicines

Two conditions apply to a medicinal product: it must be likely to be subject to a JCA, and its studies must still be in planning. The selection guidance reads "planning stage" as meaning the pivotal study has not started (health.ec.europa.eu). JCA scope depends on the product type and date: the guidance lists 13 January 2028 for designated orphan medicines, and the legislation extends JCA to other centrally authorised medicinal products from 13 January 2030. In practice, a team's expected marketing authorisation application date, not its internal development stage, decides whether the product is "likely to be subject" to JCA.

When demand exceeds planned slots, the Coordination Group selects among eligible requests. The medicines selection guidance treats the six Article 17(3) criteria as equally important, so meeting one or more can justify selection (health.ec.europa.eu). The request template has a section requiring a substantiated answer on each criterion, and developers are told to address each of them. The "first in class" test means no alternative with the same mechanism of action. A subgroup validates the selection proposal. The Coordination Group must tell developers whether it will engage within 15 working days after the period closes.

Medical devices and IVDs

The Commission and the Health and Digital Executive Agency (HaDEA) describe eligibility as class IIb or III devices and class D IVDs (hadea.ec.europa.eu), and the product must be likely to be subject to JCA under Article 7(1) (hadea.ec.europa.eu). The request template asks the developer to say whether the device is likely to be the subject of a JCA. A discrepancy deserves attention: the HaDEA notices speak of "class IIb or III", while the EMA page for the expert-panel route names class III implantable devices and class IIb active devices intended to administer or remove medicinal products (www.ema.europa.eu). Teams with a class IIb non-active device should read the template checkboxes and the selection guidance before assuming eligibility. For IVDs, a product not declared class D is not eligible.

A practical decision tree

- **Step 1, timing:** Is the pivotal study still unstarted and unsubmitted? If not, a JSC is out of scope.
- **Step 2, JCA likelihood:** Is the expected marketing authorisation or conformity route one that leads to JCA by the product's date?
- **Step 3, class check (devices):** Confirm class and whether the product is an implantable or active device before drafting.
- **Step 4, criteria:** Draft a one-paragraph, evidence-backed answer for each of the six selection criteria.
- **Step 5, fallback:** Decide in advance whether an HTACG-only JSC is acceptable if a parallel request is declined; the device template asks exactly this.

Choosing the Route: HTA-Only versus Parallel Consultation

The medicines procedural guidance, adopted by the HTACG on 22 October 2026, covers an HTACG-only JSC and, in a separate section, the parallel HTACG/EMA JSC procedure. For devices, the parallel option is HTACG together with the expert panels, available for medical devices only. *Table 1* below summarises the route

differences found in the official texts.

Dimension	HTA-only (medicines)	Parallel HTACG/EMA (medicines)	HTA-only (devices/IVDs)	Parallel HTACG/expert panels (devices only)
Duration	Approximately 4.5 months from receipt of the briefing package	Approximately 4.5 months	Confirm in current HTACG device guidance	Confirm in current HTACG device guidance
Fees	None	HTACG part free; EMA fees apply and are the same as for standard scientific advice or protocol assistance	None stated for 2026	EMA expert-panel submissions carried no fee in 2025 (www.ema.europa.eu)
Questions	PICO-structured clinical and design questions	Common template; each question addressed to HTACG, EMA or both	Device HTA-only template	Expert panel questions are clinical only (www.ema.europa.eu)
Submission channel	HTA IT Platform	HTA IT Platform plus EMA's IRIS platform	Individual link to the HTA IT Platform	Developer states in the request whether it wants the expert panel consultation in parallel (eur-lex.europa.eu)
Outputs	JSC outcome document, non-binding	EMA advice letter plus HTA outcome document (www.ema.europa.eu)	Outcome document	Outcome document plus separate expert panel advice letter

Table 1 should be read with two caveats. Device durations are not given in the sources used for this guide, so confirm them in the current HTACG device guidance before planning. The device columns rest mainly on the implementing rules and the request template rather than on a device-specific timetable. The EMA fee statement in the device column dates from 2025 and should be rechecked.

When parallel makes sense

The EMA page describes the two procedures as coordinated through synchronised timelines while preserving separate remits (www.ema.europa.eu). A parallel request is useful when regulatory and HTA questions on the same trial need one coherent answer. Quality and non-clinical questions are primarily of regulatory interest and belong with EMA. The legislation requires a developer wanting parallel EMA advice to file that request when submitting the JSC request (eur-lex.europa.eu), and the implementing rule requires the request to state whether EMA advice is sought in parallel (eur-lex.europa.eu).

Evidence on uptake is limited. EMA reported that 3 parallel JSCs from the 2025 intake were completed (www.ema.europa.eu), and the Commission counted 2 parallel among 7 JSCs started in 2026 as of June 2026 (www.ema.europa.eu). An International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Europe 2026 session abstract states that the first parallel JSCs involving HTA bodies and regulators have been completed, but it reports no findings (www.ispor.org).

When HTA-only is the better fit

An HTA-only route fits when the open questions are about comparators, outcomes and populations rather than regulatory endpoints, or when the EMA scientific advice timeline does not match the development plan. Health-economics questions may be asked, but the guidance notes the HTA advice on them is voluntary cooperation. Post-launch evidence generation can be raised only together with a study still in planning. Questions on future appraisals or reimbursement decisions are out of scope.

The Calendar: From Platform Access to Meeting

The 2026 request periods and slots

The Commission page lists four 2026 request periods, each with three briefing-document dates and three discussion-meeting weeks. The implementing regulation requires the Coordination Group to set the dates of request periods for the following year by 30 November (eur-lex.europa.eu). *Table 2* lists the periods. The day counts in the last two columns are our own arithmetic on the published dates, not figures stated by the Commission.

2026 request period	Briefing document due (2026/27)	Discussion meeting week from	Days: window close to briefing due (calculated)	Days: briefing due to meeting week (calculated)
7 January to 4 February	7 Apr, 4 May, 8 Jun 2026	6 Jul, 31 Aug, 28 Sep 2026	62 to 124	90, 119, 112
1 to 29 April (hadea.ec.europa.eu)	6 Jul, 31 Aug, 28 Sep 2026	26 Oct, 23 Nov 2026, 11 Jan 2027	68 to 152	112, 84, 105
3 June to 1 July	26 Oct, 23 Nov 2026, 11 Jan 2027	8 Feb, 15 Mar, 12 Apr 2027	117 to 194	105, 112, 91
23 September to 21 October	11 Jan, 8 Feb, 15 Mar 2027	12 Apr, 10 May, 7 Jun 2027	82 to 145	91, 91, 84

The periods and slot dates in Table 2 come from the Commission JSC page, with the first-period dates not separately quoted here because the page's table cells are not addressable text. Reading the table, the interval from briefing deadline to meeting week ranges from 84 to 119 days, roughly 12 to 17 weeks. The medicines guidance has the briefing package submitted approximately one month before the due start date. The discussion meeting falls at Day 60, and the outcome document follows at the end of a procedure of approximately 4.5 months counted from receipt of the briefing package. Working back from the meeting week therefore gets you to the meeting, not to the final outcome document. The interval from window close to the first briefing date ranges from 62 to 194 days, so a request filed early in a window faces a long wait before drafting is due. The 15-working-day decision window sits inside that gap.

Backward-planning calculator

Use this sequence, working from the meeting week you need. The dates shown are for the 2026 cycle's last period; 2027 equivalents will depend on the 2027 work programme.

- **Step 1, fix the meeting week.** Example: the week of 10 May 2027.
- **Step 2, subtract 84 to 119 days** (observed range) to find the briefing deadline: 8 February 2027 for that slot.
- **Step 3, confirm the request window.** The window must close before the briefing date; in 2026 it closed 82 to 145 days earlier for the last period (ec.europa.eu).
- **Step 4, add decision time.** Allow up to 15 working days after the window closes for the selection notice.
- **Step 5, add platform access lead time.** Notices say access can take a few days and early registration is recommended (hadea.ec.europa.eu). No fixed number is published; a working buffer of two to three weeks before the window closes is our suggestion, not an official figure.
- **Step 6, check EMA alignment for parallel requests.** EMA publishes its 2027 SAWP (Scientific Advice Working Party) meeting dates and submission deadlines for parallel requests (www.ema.europa.eu). The Commission and EMA must also exchange the list of granted parallel requests within 15 working days after a period ends.
- **Step 7, mind the late-change cut-off.** Development plan updates are considered only if received at least 10 days before the meeting (eur-lex.europa.eu).

From selection to meeting

After selection, the developer is notified, and the subgroup appoints an assessor and a co-assessor. The HTA secretariat checks the briefing package against the template and, if it does not comply, invites a resubmission within five working days (health.ec.europa.eu). Use of the HTACG template is required (health.ec.europa.eu). The secretariat then shares a list of issues structured by PICO. Developers may bring up to 12 representatives, or 14 in some cases, and slide changes after the deadline are not accepted. After the final outcome document is sent, no further developer queries about the procedure are possible. The medicines procedural guidance adopted by the HTACG on 22 October 2026 also provides an optional "watcher" role: JSC subgroup representatives may be invited to meetings between the assessor and co-assessor, without being expected to provide input (health.ec.europa.eu). Confirm that you are working from the current version before finalising timelines.

For devices, the implementing rule lets the developer request a meeting with the assessor and co-assessor on the briefing package. The device request template asks whether the developer wants a pre-submission meeting. Written responses and materials are due at least 10 days before the meeting. In the parallel route the meeting is held virtually, and a notified body chosen by the developer may be invited as an observer.

Access, Confidentiality and Document Workflow

Gaining platform access

The Commission's instructions are specific. Developers email the HTA secretariat with a request to access the HTA IT Platform and with the name, EU Login username and linked email address of a contact person (health.ec.europa.eu). Because the platform is the secure channel, the email must not include commercially sensitive information about the product or the applicant. Any such information is uploaded only on the platform. The secretariat then sends an access link and instructions (health.ec.europa.eu).

Confidentiality and channel matrix

- **Initial access email:** non-sensitive only; contact person and EU Login identity.
- **Request template and briefing package:** HTA IT Platform, with an individual link for the device template; and, for a parallel medicines request, also EMA's IRIS platform.
- **Subsequent exchange with assessors:** on the platform; the HTA secretariat is the single point of contact on HTA aspects.
- **Experts:** only individual experts who signed a confidentiality agreement are involved (eur-lex.europa.eu).
- **Patients:** patients are not obliged to disclose identity to the developer.
- **Outcome document delivery:** the HTA secretariat sends the final outcome document to the developer after HTACG approval at the end of the procedure, in line with the communicated timelines (health.ec.europa.eu).

Document and version control

Template versions matter because the template is mandatory. The medicines procedural guidance was adopted by the HTACG on 22 October 2026; the briefing-document template recommends a maximum of 10 questions and 1 to 3 pages per developer position. For devices, the request template PDF shows a June 2026 header, while the landing page shows no date for the Word file. Because the version cannot be confirmed from the page, record the file name, date shown and download date in a version log, and re-download templates when the Commission publishes a notice. For medicines, the implementing rule lets the assessor ask for an amended briefing package where questions are out of scope of a JSC.

Designing Evidence Questions: PICO and Evidence Gaps

Why PICO structure matters at JSC stage

A London School of Economics (LSE) review describes the JSC as a voluntary service providing early guidance to manufacturers on clinical trial design and evidence generation (www.lse.ac.uk). The JSC scope in the regulation names comparators, interventions, outcomes and populations, and the HTACG organises the list of issues by PICO. At JCA, the assessment scope is set through a scoping process that identifies relevant parameters (eur-lex.europa.eu). The scope is not set by the developer or by the JSC. The scoping guidance tells assessors to consult the JSC outcome document when one exists, but it also warns that JSC recommendations might no longer be applicable because of changes in the underlying situation. The PICO survey is run by the HTACG secretariat through the IT platform. A JSC therefore reduces uncertainty but does not fix the JCA PICOs.

The multi-stakeholder methodology literature identifies the same gap, listing as a priority the need to establish a link between JSCs, potential PICOs and JCA preparations (pmc.ncbi.nlm.nih.gov). A consultancy review of the first JCA year described the 90-day window between release of the PICO framework and dossier submission as extremely tight (www.iconplc.com).

PICO and evidence-planning checklist

Build one row per question before drafting prose. The following inventory and checklist is a working template, not an official form:

- **Population:** Which subpopulations might national policy questions isolate? The scoping guidance notes a specific PICO might comprise only a subpopulation of the study population. Plan stratification and subgroup analyses accordingly.
- **Intervention:** Which dose, regimen or device configuration will be in the pivotal study, and is it the one intended for marketing?
- **Comparator:** Is there a single globally acceptable comparator? An EFPIA-hosted oncology paper argues there is no widely agreed standard of care in oncology, which can make comparator choice hard (www.efpia.eu). Where direct comparison is not available, the HTACG Q&A prefers anchored indirect comparisons, and the quantitative methods guideline requires a connected evidence network.
- **Outcomes:** Are the outcomes patient-relevant? The outcomes guidance says surrogate outcomes may or may not reflect a direct patient-centred benefit.
- **Design:** For medicines, the regulation says outcome advice shall address directly comparative randomised, blinded studies with a control group where appropriate (eur-lex.europa.eu).
- **Evidence timing:** Which analyses will exist at the data cut used for a later dossier? The HTACG Q&A says all available evidence must be in the initial dossier.
- **Out-of-scope items:** Reimbursement, pricing and appraisal questions.

Evidence from simulated and live PICO exercises

A review of 14 publications covering 35 PICO exercises found an average of 7 countries participating per exercise and 8 consolidated PICOs per analysis (www.ncbi.nlm.nih.gov). A separate simulation generated 67 PICOs, reflecting the anticipated perspectives of 25 countries (www.ncbi.nlm.nih.gov). These figures are simulations and early practice, not guarantees of what a JCA scope will contain, but they show why a JSC question list should anticipate subpopulation and comparator variation. The same body of literature calls for clarity on the PICO identification process and its impact on JCAs (pmc.ncbi.nlm.nih.gov).

Cap and prioritise

The medicines template recommends no more than 10 questions. A practical prioritisation rule is to rank questions by the cost of getting them wrong after the pivotal study starts: comparators and primary outcomes first, then subgroup and sensitivity questions, then exploratory items. The request template also requires at least minimum information on the population, intervention, comparator and outcomes to be annexed to the request.

Briefing-Document Assembly and Review RACI

Assembly sequence

1. **Draft the question list first,** then the developer position under each question, because the template pairs each question with a position.

2. **Write the development-plan summary** consistently with the request template's minimum PICO annex.
3. **Assign each question to HTACG, EMA or both** if the route is parallel.
4. **Run a template-compliance check** before upload, since non-compliant packages are returned for resubmission within five working days.
5. **Freeze the version** and keep a clean and a tracked copy for any amendment round.
6. **Prepare the meeting pack:** written response to the list of issues, slides, participant list, up to 12 representatives.

Review RACI

Table 3 is an illustrative RACI (Responsible, Accountable, Consulted, Informed) matrix. It is the author's suggestion for cross-functional handoffs and is not drawn from any official source. The roles are generic; adapt them to your organisation.

Work item	Responsible	Accountable	Consulted	Informed
Eligibility and selection narrative (six criteria)	Market access	Head of market access	Clinical development, regulatory	Executive sponsor
EU Login set-up and platform access email	Regulatory operations	Regulatory lead	Legal (confidentiality check)	Market access
PICO and question inventory	HEOR	Market access lead	Biostatistics, clinical	Regulatory
Study design sections	Clinical development	Development head	Biostatistics, HEOR	Market access
Comparator and indirect-comparison rationale	Biostatistics	HEOR lead	Clinical, regulatory	Market access
Regulatory questions (EMA, IRIS; or notified body for devices)	Regulatory affairs	Regulatory lead	Quality, clinical	HEOR
Version log and template check	Regulatory operations	Regulatory lead	Market access	All
Meeting pack and rehearsal	Market access	Market access lead	Clinical, HEOR, regulatory	Executive sponsor
Minutes and handoff to JCA planning	Market access	Market access lead	HEOR, regulatory	Clinical

Three points explain the table. The HTA secretariat is the single point of contact on HTA aspects, so one internal owner should hold the platform account. Slide and participant changes after the deadline are not accepted, so the meeting pack needs a hard internal freeze. Late plan changes are considered only if received at least 10 days before the meeting, which makes the biostatistics and clinical sign-off dates the critical path.

Outputs, Limits and the Downstream JCA Handoff

What the JSC delivers

In the predecessor EUnetHTA early dialogues, patient involvement was primarily done by interviewing a national patient representative (www.cambridge.org). Under the Regulation the process is more formal. The outcome is an outcome document with scientific recommendations. It gives rise to no legal effects for Member States, the Coordination Group or the developer, and it does not prejudice the later JCA. The guidance repeats that, given the preliminary nature of the consultation, advice is not legally binding.

What changes in the JCA dossier

The one explicit link is documentary. A product that had a JSC must explain any deviation from the recommended evidence in the dossier (eur-lex.europa.eu), and the dossier template guidance has the JSC recommendations documented in Appendix D.9. The HTACG Q&A adds that the developer must address all PICOs in the scope. The assessors for a JCA differ from those who ran the JSC, so the developer cannot rely on continuity of personnel.

The JSC-to-JCA evidence reuse map below shows where each planning decision resurfaces:

- **JSC question on comparator:** resurfaces as a scoped PICO comparator; expect national variation.
- **JSC advice on endpoints:** resurfaces in the outcomes assessment; surrogate outcomes remain a judgment for Member States.
- **JSC advice on design:** resurfaces in dossier appendix D.9 and any deviation explanation.
- **JSC meeting minutes:** are the developer's own record and should be filed with the evidence plan.
- **Scoping timing:** under the implementing rules the JCA scope is finalised within 10 days after the CHMP adopts its list of questions, and the dossier deadline is 100 days from notification of the first request (eur-lex.europa.eu).

Limits

Three limits stand out. A Dutch HTA body paper also notes that the European JSC is more extensive than the Dutch early dialogue (pmc.ncbi.nlm.nih.gov), which matters for teams used to national advice. Capacity: the 2026 plan was 8 to 12 medicine JSCs and 2 to 5 device JSCs, and the Dutch HTA body reported that, owing to capacity constraints, it decided to concentrate on the JCA (pmc.ncbi.nlm.nih.gov). Scope: health-economics questions are voluntary. Timing: advice reflects the situation at the time of the JSC.

Data Analysis and Evidence

Volumes and capacity

As of 29 November 2026, official counts are fragmentary and use different definitions, so they should not be added across sources. The Commission's June 2026 update reported 7 JSCs started in 2025, all completed (www.ema.europa.eu), and 7 new JSCs started in 2026, 2 of them parallel. It also reported that 12 different Member States took assessor or co-assessor roles (www.ema.europa.eu). An earlier February 2026 presentation reported 2 request periods in 2025 and 4 planned for 2026 (www.ema.europa.eu). The December

2025 Commission slide stated "max 12 requests for medicines and 5 requests for medical devices" for 2026 (www.ema.europa.eu). Compare that with the 2026 work programme range of 8 to 12 and 2 to 5, and the pre-application survey in which companies identified over 50 products likely to request advice (www.eucope.org).

The programme says the subgroup will work to raise those numbers over time and that the subgroup meets monthly except August. Taken together, the data suggest that demand has exceeded slots, but no official request-count for the 2026 periods was found, so the selection rate cannot be calculated.

JCA context for the handoff

The Commission counted 15 ongoing medicine JCAs and 4 published reports on 6 October 2026 (ec.europa.eu), and 21 ongoing with five published reports by 23 November 2026 (ec.europa.eu). The first device JCAs started on 6 October 2026 (ec.europa.eu), and a third device was selected on 23 November 2026 (ec.europa.eu). Device selection is expected quarterly (ec.europa.eu), and not every device with an expert panel opinion is subject to JCA. A JCA report on a breast cancer medicine, published on 6 November 2026, had been endorsed by Member States on 19 August 2026 (ec.europa.eu).

Predecessor benchmark

A consultancy review reports the Coordination Group anticipated eight to 12 JSCs for medicines and two to five for devices in 2026 (www.iconplc.com). A trade-press report of the first six months noted that up to 25 JCAs might be initiated in the first year (globalforum.diaglobal.org). Under EUnetHTA Joint Action 3, 113 pharmaceutical early-dialogue requests were received and 38 conducted, and its authors concluded early dialogues had been established as an efficient, successful product (www.cambridge.org). Earlier EMA and EUnetHTA 21 guidance put the whole parallel procedure at approximately four months (www.ema.europa.eu). Under the current rules, approximately 4.5 months is the stated figure.

Source discrepancies

- **Parallel JSC count for 2025:** the Commission cited 7 JSCs selected in 2025, while EMA reported 3 parallel JSCs completed from the 2025 intake; no source reconciles the two.
- **Device class wording:** "class IIb or III" in notices (ec.europa.eu) versus narrower class lists on the EMA expert-panel page.
- **Template dates:** June 2026 on the PDF header; the landing page shows no date for the Word file, so log the file name and download date.
- **JCA counts:** definitions differ between the October and November updates.

Worked Examples (Hypothetical Examples)

Medicine (Hypothetical Example)

A mid-sized biotech plans a pivotal randomised study of a new active substance in an oncology indication, with a marketing authorisation application expected in 2028. The pivotal protocol has not been submitted anywhere, which meets the "planning stage" reading. The team asks whether to seek HTA-only or parallel advice. Its open questions include the comparator (two standards of care across Member States), a surrogate

primary endpoint, and a subgroup that might form its own PICO. It decides on parallel advice because the surrogate question is also regulatory, while keeping quality questions with EMA. It sets a target meeting in the week of 10 May 2027 and works backward to a briefing date of 8 February 2027. In this hypothetical, the team confirms in its request that an HTACG-only JSC would be acceptable if the parallel request were declined, mirroring the question in the device template. Nothing here implies selection or that the advice would be accepted.

Device (Hypothetical Example)

A manufacturer of an implantable class III device plans a clinical investigation. The device is a candidate for expert panel clinical evaluation consultation and possibly a JCA, but not every such device is selected. The team chooses the parallel HTACG/expert panels route because the investigation design affects both the notified body and HTA bodies; it indicates this in the request. It notes the EMA page's rule that the final briefing document must follow the published timetables (www.ema.europa.eu), and that expert panel questions are clinical only. It invites its notified body as an observer, which the rules allow. Because parallel advice is for devices only, an IVD manufacturer in the same position would use the HTA-only route and first confirm class D status.

Implications and Future Directions

The 2027 cycle is the next decision point. The rules require the Coordination Group to set the following year's request periods by 30 November and at least three periods a year for both medicines (eur-lex.europa.eu) and devices. The 2026 work programme planned to approve the 2027 programme by that date. Teams should check the Commission page for the published 2027 periods before building plans on assumed dates.

Capacity is likely to remain the binding constraint. The programme aims to raise JSC numbers over time, and the regulation requires the Commission to review whether a fee-paying mechanism is needed. This guide cannot predict policy, so budget for both fee-free and fee-bearing outcomes in long-range plans.

JSC planning and JCA readiness converge. The Commission's expansion of JCAs, the first device JCAs and quarterly device selection mean evidence plans will be judged against live assessments. A consultancy review reports that the "PICO anxiety" predicted during simulations remains a reality in live assessments (www.iconplc.com). Teams that treat the JSC question list as the seed of their PICO inventory will find it easier to answer "all PICOs" later.

Operational maturity is an advantage. A version log, a single platform owner and a frozen meeting pack cost little. IntuitionLabs' view, as an advisor, is that most delays in this process arise from handoffs between functions rather than from the science; this is an editorial perspective, not a measured finding.

Where professional advice matters. Eligibility, confidentiality and regulatory strategy decisions are consequential. Consult your regulatory counsel and the official guidance before filing; this article was not reviewed by any professional.

Frequently Asked Questions (FAQs)

What is the EU HTA joint scientific consultation process?

A developer requests a JSC in a published period, is selected if capacity requires, submits a briefing package, receives a list of issues, attends a virtual meeting and receives a non-binding outcome document.

How do I submit a JSC request?

Email the HTA secretariat for platform access with your EU Login details and no sensitive content. Then upload the request on the HTA IT Platform.

Which joint scientific consultation timeline applies?

The HTACG timeline is approximately 4.5 months, with slots published per request period.

What is the EMA parallel route?

It is a JSC run in parallel with EMA scientific advice, with a request to both and an EMA advice letter plus an HTA outcome document.

Are consultations free?

The HTACG JSC is not subject to fees (health.ec.europa.eu). HaDEA's January 2026 notice said there is no fee for the service (hadea.ec.europa.eu).

How does PICO scoping relate to the JSC?

JSC advice covers the same four parameters, but the JCA scope is set later through a separate process.

Is there a 2027 programme?

It was due by 30 November 2026; no published 2027 periods were found when the Commission's JSC page was last checked on 29 November 2026, so check that page for updates.

Conclusion

The JSC is a narrow, time-boxed, non-binding procedure, and its value depends on disciplined preparation. The key choices are route, slot and question design. For medicines, the HTACG-only and parallel routes have comparable durations, so the decision turns on whether regulatory questions share the trial design. For devices, the parallel route exists only for medical devices. The final 2026 window closed on 21 October 2026, and teams that missed it should plan for the 2027 periods, the dates of which should be confirmed on the Commission page.

The operational lessons are consistent. Give platform access time to arrive, keep sensitive content off email, use the mandatory templates, cap and rank the questions, freeze the meeting pack, and carry the outcome into the dossier with an explanation for any deviation. None of this guarantees selection or a particular result, and the outcome carries no legal effect.

Source links

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AI consulting and adoption

Our AI enablement services cover readiness assessments, use-case selection, governance and policies, team workshops, adoption measurement and ongoing advisory support. We help organizations structure the information layer behind AI: source material, context, permissions and maintained knowledge that make generated answers useful and reviewable. Private LLM inference and hosted AI options support teams evaluating how to operate AI with appropriate control over their data and infrastructure.

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IntuitionLabs develops custom software for pharma and biotech, integrates enterprise systems, and builds data engineering and business intelligence solutions. Areas of focus include AI agents, regulatory research, medical writing, medical affairs, CMC information, competitive intelligence and clinical-document workflows. Our eTMF intelligence work includes cross-system reconciliation and inspection-readiness support.

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