Scientific and Clinical Advances Advisory Committee (SCAAC) – Minutes

Wednesday 4th February 2026, 10:00am – 2:25pm

Virtual Meeting: Microsoft Teams

Authority members	Present	Tim Child (Chair) Stephen Troup (Deputy Chair) Christine Watson Geeta Nargund Zeynep Gurtin Frances Flinter
External advisers	Present	Anthony Perry Scott Nelson Alison Campbell Peter Rugg-Gunn Veronique Berman Ying Cheong Asif Muneer Sarah Martins Da Silva Laura Shallcross
Speakers	Present	Margherita Yayoi Turco (Research Group Leader at the Fridrich Miescher Institute for Biomedical Research in Basel, Switzerland) for item 6
Executive	Present	Julia Chain (Chair of Authority) Peter Thompson (Chief Executive) Clare Ettinghausen (Director of Strategy and Corporate Affairs) Rachel Cutting (Director of Compliance and Information) Dina Halai (Head of Policy, Scientific) Rebecca Taylor (Scientific Policy Manager) Mina Mincheva (Policy Manager, Scientific) Dharmi Deugi (Scientific Policy Officer; Committee Secretariat)
Observers	Present	Several HFEA staff observed the meeting as relevant to their role or induction into the organisation.

1. Welcome, apologies, declarations of interest

1.1. The Chair welcomed the Committee and reminded members of the advisory role of the SCAAC, highlighting that members should advise the HFEA on any significant implications for licensing and regulation arising out of scientific and clinical developments in assisted conception, embryo research and related areas.

1.2. Declarations of interest were made by:

- Alison Campbell (Chief Scientific Officer at Care Fertility and Clinical Advisor at U-Polid Biotechnologies) – Care Fertility clinics offer calcium ionophore.
- Peter Rugg-Gunn (Group Leader and Head of Public Engagement at The Babraham Institute) – Involved in research related to endometrial organoids.
- Stephen Troup (Fertility Consultant) – Provides consultancy advice to Myma Medical LTD (developing robotic ICSI system).
- Ying Cheong (Professor at University of Southampton and consultant at University Hospital Southampton) – Previously advised AI company, A-Life.
- Sarah Martins Da Silva (Clinical Reader at the University of Dundee, clinical lead for NHS Tayside fertility services and Person Responsible for Ninewells Assisted Conception Unit) - Ninewells Assisted Conception Unit offer calcium ionophore.
- Geeta Nargund (Lead Consultant for Reproductive Medicine at St George's Hospital NHS Trust) – Appointed as life peer at the House of Lords.

1.3. No further conflicts of interest were declared.

2. Matters arising

2.1. The Executive updated the Committee on the matters arising as laid out in the matters arising paper for this meeting.

2.2. No further comments were made.

3. Chair's business

3.1. The Chair noted that the Executive has appointed three external expert biostatisticians following an open recruitment process. They will assist the SCAAC by undertaking evidence reviews on the efficacy and safety of fertility treatment add-ons when necessary.

3.2. The Chair informed the committee that the Women and Equalities Committee (WEC) launched a new inquiry into egg and embryo donation and freezing. The purpose of the inquiry is to consider whether the current regulatory framework has adequate safeguards to protect individuals from exploitative practices and whether there is sufficient information about these procedures. The paper and minutes from the June 2025 SCAAC discussion on 'Health outcomes for ART patients (including gestational surrogates and egg donors)' was used to inform the HFEA's written evidence along with HFEA data on egg donors and gestational surrogates.

3.3. Following agreement with the voting members of the SCAAC, the Authorised Processes (AP) list was amended to add Preimplantation Tissue Typing (PTT).

3.4. Furthermore, a clarification has been added to the authorised process of 'In vitro maturation' to explain that this process is to only be applied to oocytes that are retrieved from antral or pre-ovulatory follicles – mirroring the standard uses of IVM and rescue IVM, as seen in current clinical practice, and clarifying that it does not refer to IVM of sperm.

4. Relevant public health developments and research findings

4.1. The Chair informed the Committee that this item provides members with the opportunity to highlight research relevant to the interests and role of the SCAAC, including those relevant to the horizon scanning topics that SCAAC have prioritised, the 'watching brief' topics (February 2025 horizon scanning paper), and for treatment add-ons ratings.

4.2. The Committee considered the following research papers and made the following comments:

- Preimplantation Genetic Testing for Aneuploidy Versus Morphological Selection in Women Aged 35-42: Results of a Pilot Randomized Controlled Trial

4.2.1. This was a study of interest in relation to treatment add-ons, however there were no statistically significant outcomes.

4.2.2. Members flagged that the availability of these types of studies in the public domain is concerning from a patient perspective as it encourages patients towards certain types of treatments despite limited evidence.

- Elective fertility preservation: a national database study on trends in oocyte cryopreservation and oocyte utilization over a 5- to 7-year follow-up period

4.2.3. The Executive noted that the return for use of cryopreserved oocytes falls under the scope of the topic, 'Health outcomes for ART patients (including gestational surrogates and egg donors)'.

4.2.4. The committee noted the study.

- MHRA-led study reveals major inconsistencies in global microbiome research / DNA reference reagents isolate biases in microbiome profiling: a global multi-lab study

4.2.5. The committee noted the study.

- World Health Organisation: Guideline for the prevention, diagnosis and treatment of infertility

4.2.6. The committee noted the guideline.

- Zishen Yutai Pill increased live births in advanced maternal age women: a RCT

4.2.7. The committee noted that the study was underpowered, and no elevated risk of maternal or neonatal adverse events was reported.

- Preprint paper: Restoring Shugoshin 1 reduces chromosome errors in human eggs

4.2.8. The Chair stated that the study was reported in the media, flagging concerns from a commercial perspective especially given the small sample size.

- The British Fertility Society (BFS) Policies and Practice group have drafted a paper on 'Optimising IUI: Evidence-based guidance for use of add-ons and variations in IUI treatment'

4.2.9. The committee noted that this was open to review by BFS members until the 20th of February 2026.

- Natural ovulation versus programmed regimens before frozen embryo transfer in ovulatory women: multicentre, randomised clinical trial

4.2.10. The committee noted the study.

- Modelling human embryo implantation in vitro
- A 3D in vitro model for studying human implantation and implantation failure

4.2.11. A member commented on the consistency across both papers reporting on the creation of new models of implantation using endometrial cells derived from healthy donors. The studies attempted to create multi-layered multi-tissue models whereby including endometrial cell types provides a better environment for in vitro embryo development. Although embryos were not developed after day 14, the research allowed visualisation of some features of human development, such as, the early stages of placenta formation and interaction with the endometrium. It was noted that these models can be used as discovery platforms for improving implantation rates.

- Fertilization Triggers Early Proteomic Symmetry Breaking in Mammalian Embryos

4.2.12. The committee noted the study.

- Genetic landscape of human oocyte/embryo defects

4.2.13. The committee noted the study.

5. Prioritisation of horizon scanning topics and committee workplan 2026/2027

5.1. The horizon scanning process highlights relevant issues in fertility treatment and embryo research identified from journal articles, conference attendance, and expert recommendations.

5.2. The Executive highlighted some new changes to the horizon scanning process including:

- Literature reviews of all prioritised topics will be conducted every 3 years.
- Literature search articles will be processed through a retraction tool.
- Literature searches will not be conducted for watching brief topics.
- Literature searches will not be restricted to English language only.

5.3. The Committee made the following comments and recommendations:

5.3.1. In light of research developments in genome editing in human embryos a member flagged the importance of the medium priority topic ‘Germline/heritable genome editing’.

5.4. **Recommendation:** The Executive to bring the discussion on the topic of ‘Germline/heritable genome editing’ forward in the workplan.

5.4.1. The Executive noted that different types of pre-implantation genetic testing as well as pre-implantation testing for polygenic disorders (PGT-P) will be considered within the scope of the ‘Emerging technologies in gamete and embryo testing’ topic.

5.4.2. Members were informed that updated guidance for clinics on permitted embryo testing under the HFE Act will be published later this year.

5.4.3. The Committee agreed that 'Impact of long-term cryopreservation of gametes and embryos' should remain a medium priority topic, particularly in light of increasing patient interest. This would also allow time for further research to be published before the topic is discussed again.

5.4.4. Members agreed that 'Understanding the genetic basis of infertility' should be moved from the watching brief to a medium priority topic, reflecting recent research developments.

5.5. **Recommendation:** The Executive to update the topic prioritisation list to move the topic of 'Understanding the genetic basis of infertility' from the watching brief list to medium priority.

5.5.1. Members agreed with the remainder of the horizon scanning topic prioritisation list and watching brief topics.

5.5.2. As part of the horizon scanning process, a member proposed the potential use of AI to support literature reviews of prioritised topics and filter for high quality research papers to reduce the volume of low-quality evidence.

5.5.3. Members raised concerns regarding the use of AI tools, noting variability in performance and limitations in reliability. Particular issues highlighted were in relation to the "black box" nature of such tools, which presents challenges for quality assurance and transparency in decision-making. Members also noted risks including the hallucination of references and the potential reinforcement of existing social biases. It was noted that appropriate implementation would require collaboration with computer science expertise.

6. Reproductive organoids

6.1. The Chair welcomed external speaker, Dr Margherita Yayoi Turco, to present on female reproductive tract organoids, specifically endometrial and placental organoids.

6.2. The Committee were reminded that the topic of reproductive organoids was added to the SCAACs horizon scanning prioritisation as a medium priority topic in February 2025. The research developments summarised by the paper include those published between January 2015 and December 2025 (10-years).

6.3. The Committee made the following comments and recommendations:

6.3.1. The external speaker reported observing findings consistent with current research, noting that the extent of organoid differentiation and expansion varies following hormone application. This variability may reflect normal biological variation or differences in source material, such as enrichment of specific cell types within tissue samples.

6.3.2. In response to a question regarding the incorporation of vasculature or immune cells into reproductive models, the speaker clarified that unlike other organoid systems (eg intestine), there are currently no stable co-culture systems with immune cells for reproductive models such as the endometrium. This was attributed to challenges, such as, maintaining immune cells in culture without long-term phenotypic changes and replicating appropriate hormonal environments.

6.3.3. The speaker noted that some progress has been made in co-culturing reproductive organoids with stromal cells, which may support future developments involving immune cell co-culture systems.

6.3.4. The speaker highlighted that Epidermal Growth Factor (EGF) levels increase following hormone withdrawal from the organoids, but when the organoids are broken up and menstruation is mimicked, an increase in wound healing factors is observed. The protocols used allows for decoupling of factors associated with the menstrual cycle in a controlled manner. It was further noted that the epithelium produces significant levels of angiogenic factors during breakdown and regeneration. These factors may support the development of co-culture systems; for example, when combined with endothelial cell lines, they have been shown to promote wound healing. This approach is helping to elucidate key cellular interactions relevant to development.

6.3.5. The speaker noted ongoing research in the placental field using different cell lines to study extracellular vesicles. It was highlighted that reproductive organoids may offer potential to investigate interactions between the endometrium and embryo, including the role of extracellular vesicles.

6.3.6. The speaker also expressed that current reproductive organoid models may have the potential to support development beyond 14 days. The epithelial compartment of bioengineered endometrium can be maintained until at least 28 days.

6.3.7. The speaker further commented that as reproductive organoid models are derived from human tissue samples, ethical considerations particularly regarding the extent to which embryos can be developed using these models is important due to the 14-day rule.

6.3.8. The speaker highlighted that a coordinated, collective effort would be required to create biobanks of reproductive organoids.

6.3.9. Members noted that in the context of male reproductive biology, research is currently more focused on stem cell engineering approaches to generate functional sperm, rather than development of testicular organoid models. In addition, microfluidic systems are being used to recapitulate aspects of vascularisation within the endometrium to study sperm migration and drug effects.

6.3.10. The Committee noted that the female and male reproductive systems differ significantly, with distinct and specialised research approaches, and therefore agreed that expertise is not readily transferable between the two areas.

6.4. **Recommendation:** The Committee agreed to split the topic of reproductive organoids into female reproductive organoids and male reproductive organoids.

6.4.1. The Chair thanked Dr Margherita Yayoi Turco for her presentation and contribution.

7. Artificial intelligence, robotics and automation in fertility treatment

7.1. A summary of the paper highlighting the key developments in the application of AI, robotics and automation as part of fertility treatment was presented to the Committee. Notable advancements

in predicting treatment outcomes, oocyte and embryo selection as well as the use of large language models (LLMs) were overviewed.

7.2. The Committee were reminded that this topic was last discussed in February 2024 and that in 2024 the HFEA undertook a scoping project in uses of AI in fertility treatment, including mapping the UKs regulatory landscape.

7.3. The following comments and recommendations were made:

7.3.1. A member noted that the summaries provided in the paper along with the categorisation of different themes was useful.

7.3.2. Members commented that a key challenge for LLMs is their integration into clinical practice, particularly given the current regulatory framework for medical devices overseen by the Medicines and Healthcare products Regulatory Agency (MHRA). It was noted that not all AI tools are classified as medical devices, which creates additional complexity for oversight.

7.3.3. In this context, members flagged concerns regarding chatbots using Retrieval-Augmented Generation (RAG), noting the potential for misleading information despite not falling within existing regulatory frameworks.

7.3.4. Members also discussed the use of machine learning to optimise treatment outcomes. It was noted that, except for EmbryoScope iDAScore software, most systems used to predict treatment aspects, such as trigger optimisation and stimulation monitoring have not undergone validation through conventional pathways such as randomised controlled trials (RCTs). Most models have only been subject to temporal or internal validation, limiting the robustness of the clinical evidence base.

7.3.5. In light of these concerns, members highlighted the importance of establishing clear policies and standard operating procedures (SOPs), particularly in relation to validation standards.

7.3.6. A member further noted the lack of RCTs involving diverse populations, which may introduce bias and limit the generalisability of findings.

7.3.7. Concerns were also raised regarding data governance, including compliance with the UK General Data Protection Regulation (GDPR), control over data held by medical devices, and the management of data repositories.

7.3.8. Members discussed the use of AI in clinics, noting that some providers are advertising AI-based technologies for evaluating egg quality, including MAGENTA™ and VIOLET™. It was suggested that a review of clinic websites could provide further insight into the current use of AI in the UK, although it was acknowledged that clinic websites are not a comprehensive way of auditing the use of AI in UK clinics.

7.3.9. The Executive noted that as part of the project on the uses of AI in fertility treatment, a scoping exercise of commercial software available worldwide for various processes, such as, sperm selection, and oocyte and embryo quality was performed. Furthermore, the inspectorate also provide regular feedback on novel uses of AI or any related concerns identified during inspections.

7.3.10. The Executive additionally reported that findings from a previous survey in 2024 completed by a small number of HFEA Patient Engagement Forum members indicated that most of them were not aware of the use of AI in fertility treatment.

7.3.11. From a patient perspective, a member noted mixed views on the use of AI in treatment pathways. While some patients are supportive, others have concerns about its role in fertility treatment clinical decision-making. Members emphasised the importance of how AI is presented and marketed, particularly given the limited evidence base and the potential to create unrealistic expectations.

7.3.12. It was further noted that, as part of ongoing reviews of interim inspection themes, the inspectorate has incorporated questions on AI being used as part of treatment during clinic inspections. These focus on areas including AI use in the clinic, validation processes, staff training, and the provision of patient information. AI as medical devices continues to be in the remit of the MHRA.

7.3.13. Whilst AI may enhance clinical knowledge, concerns arise where there is reliance on AI for decision-making. It was emphasised that clinical decisions should remain the responsibility of qualified professionals, such as consultants and embryologists. This is in line with guidance provided by the General Medical Council.

7.3.14. A member highlighted that, despite the importance of validation, AI may offer operational benefits in clinical settings. It was suggested that consideration be given to how safe, non-invasive AI tools could be implemented appropriately. In relation to automation, members commented that some laboratory processes (e.g. involving embryoscopes and microscopes) are already automated.

7.3.15. Members considered whether some uses of AI tools could be considered as treatment add-ons, particularly where patients are charged for its use.

7.3.16. The rapid pace of development of robotic surgery in other areas of medicine was noted. In terms of fertility treatment, simpler processes, such as dish preparation, may be relatively straightforward to validate, particularly where materials are certified. However, fully integrated end-to-end robotic systems remain some way from validation and routine clinical implementation.

7.3.17. Members discussed the difficulty in distinguishing between AI and automation. It was noted that in comparison to AI, research on automation and robotics is relatively limited, and it was therefore suggested that the topics be separated to ensure appropriate focus.

7.4. **Recommendation:** The Committee agreed to split the topic of AI from automation and robotics.

8. Review of the authorised use of calcium ionophore

8.1. The committee were reminded of the delegated responsibilities of the SCAAC in relation to the authorised processes (AP) list, the requirement to maintain the list, and the procedure to authorise new processes.

8.2. The Executive highlighted that the use of calcium ionophore in fertility treatment is being brought to the attention of SCAAC to confirm that the current inclusion of calcium ionophore on the authorised processes list does not include its use for embryo development and to consider whether a novel processes application is required for this use.

8.3. The Committee made the following comments and recommendations:

8.3.1. Members discussed the biological basis of egg activation, noting that during fertilisation sperm-induced calcium influx takes place followed by calcium oscillations within the oocyte which are essential for egg activation and subsequent development. It was noted that in some patients this process is impaired, preventing normal development. In such cases, calcium ionophores may be used to artificially induce egg activation.

8.3.2. A member commented that in 2018, a clinic adopted a cautious approach to the use of calcium ionophore for embryo development provided the limited evidence available at the time. The clinic has since generated data from a small cohort of patients where the intervention was used in specific circumstances (eg absence of blastocyst development). This data suggested an improvement in blastulation rates; however, the findings remain unpublished.

8.3.3. The evidence base for the use of calcium ionophores to support embryo development is limited, consisting primarily of small retrospective studies and there remain uncertainties regarding the intracellular persistence of calcium ionophores following treatment. It was also highlighted that such use is off-label relative to the product's licensed indication.

8.3.4. Concerns were raised regarding both safety and efficacy. Members noted that animal studies using mice have indicated potential adverse effects associated with calcium ionophore use for blastocyst development, including DNA damage and altered energy metabolism.

8.3.5. It was further highlighted that the mechanism by which calcium ionophore facilitate calcium entry into cells does not replicate physiological processes observed during fertilisation. Members noted that calcium signalling is a critical tightly regulated second messenger system involved in a wide range of downstream processes, including gene transcription, and that prolonged or altered exposure may have unintended implications for development.

8.3.6. A member flagged that alternative mechanisms of oocyte activation have been demonstrated experimentally, suggesting that calcium signalling may not be the only pathway involved[1]. Overall, members agreed that further clinical evidence is required to better understand the safety and efficacy of calcium ionophore use in this context.

8.3.7. Members expressed that whilst similar methodologies are used, the use of calcium ionophore is permitted for egg activation only. This is consistent with professional body (ARCS/BFS) guidelines.

8.3.8. The Executive noted that in relation to the AP list, where it states that clinics are expected to follow professional body guidance there may be circumstances in which deviation is justified, for example where guidance is outdated, new evidence has emerged, or where clinics have undertaken appropriate validation or risk assessment. However, it was reiterated that any process not included on the AP list is prohibited in clinical practice.

8.3.9. The Committee were further informed that clinics may apply for novel processes to be added to the AP list following consideration by the SCAAC. Where approved, such processes are subject to an enhanced reporting period, during which clinics must provide evidence relating to safety. This evidence is subsequently reviewed to determine whether the process should remain on the AP list.

[1] Full-term mouse development by abolishing Zn2+-dependent metaphase II arrest without Ca2+ release | Development | The Company of Biologists

8.3.10. It was clarified that once included on the AP list, a process can be used by any clinic unless specific conditions are applied by the SCAAC, which could include limited use by a certain clinic or clinics.

8.4. **Decision:** The Committee confirmed that:

- The current inclusion of calcium ionophore on the authorised processes list does not include its use for embryo development and clinics should therefore not use it for this purpose.
- A novel process application for the use of calcium ionophore for embryo development would need to be submitted for SCAAC's consideration and approval.

9. Committee effectiveness review

9.1. The Annual Review of Committee Effectiveness was led by the Chair. A summary of feedback was presented at the March 2026 Authority meeting.

10. Any other business

10.1. The HFEA published a blog explaining why PGT-P is not lawful in the UK.

11. Meeting summary and close

11.1. The Chair closed the meeting by thanking the Executive for drafting the papers and thanking Molly Davies for her support to the Committee while working at the HFEA.

11.2. The next SCAAC meeting will be held on Wednesday 3rd June 2026.

12. Chair's signature

I confirm this is a true and accurate record of the meeting.

Chair: Tim Child

Date: Tuesday 24th March 2026

13. Annex A: Revised Committee Workplan 2026/27

13.1. The below table presents the agreed workplan of the SCAAC for 2026/27.

Priority topic	Item	External speaker?	Last discussed	Meeting
AI, robotics and automation in fertility treatment	Literature review	No	February 2024	February 2026
Reproductive organoids	Literature review	Yes (agreed)	N/A – new topic	February 2026
Horizon scanning prioritisation and agreeing workplan for 2026/27	Workplan review	No	February 2025	February 2026
Emerging technologies in embryo and gamete testing	Literature review	No	June 2024	June 2026
Impact of the microbiome on fertility treatment outcomes	Literature review	No	June 2025	June 2026
Treatment add-on rating – sperm DNA fragmentation testing	Evidence review report	Yes (biostatistician)	June 2025	June 2026
Treatment add-on rating – microbiome testing	Evidence review report	Yes (biostatistician)	June 2025	June 2026
Stem cell-based embryo models (SCBEM)	Literature review	No	October 2024	October 2026
Scientific considerations relevant to the 14-day rule	Literature review	No	October 2024	October 2026
In vitro derived gametes (IVGs)	Literature review	No	October 2024	October 2026
Health outcomes in children born from ART (including impact of culture media)	Literature review	No	February 2025	February 2027
Mitochondrial donation	Literature review	TBC	October 2024	February 2027
Add-on data collection from clinics (TBC)	Proposal & discussion	No	N/A	N/A
Horizon scanning prioritisation and agreeing workplan for 2027/28	Workplan review	No	February 2026	February 2027
Understanding the genetic basis of infertility	Literature review	No	N/A	June 2027
Health outcomes for ART patients (including gestational surrogates and egg donors)	Literature review	No	June 2025	June 2027
Impact of long-term cryopreservation	Literature review	No	February 2025	June 2027

13.2. Should the priorities of the Authority change, alterations to the workplan may be agreed independently with the SCAAC Chair.

14. Annex B: Revised Horizon Scanning Topic Prioritisation

14.1. The below table presents the agreed horizon scanning topic prioritisation list.

High	Medium	Low	Watching brief
Alternative methods to derive embryonic and embryonic-like stem cells	Germline/heritable genome editing	Male reproductive organoids	Artificial wombs for early or whole gestation (ectogenesis)
Artificial Intelligence (AI) in fertility treatment	Impact of long-term cryopreservation of gametes and embryo		Impact of environmental toxins on fertility treatment outcomes
Emerging technologies in gamete and embryo testing	Impact of the microbiome on fertility and fertility treatment outcomes		Impact of stress on fertility treatment outcomes
In vitro derived gamete (IVGs)	Testicular tissue transplantation to restore fertility in males		Use of ICSI for non-male and mild-male factor infertility
Mitochondrial donation	Female reproductive organoids		
Scientific considerations relevant to the 14-day rule	Robotics and automation in fertility treatment		
Stem cell-based embryo models (SCBEM)	Understanding the genetic basis of infertility		
Health outcomes in children born from ART (including the impact of culture media)			
Health outcomes for ART patients (including gestational surrogates, egg donors, and the impact of treatment using donated eggs)			