

10th APRIL 2026

ISTITUTO DEGLI INNOCENTI, AULA POCCETTI - FLORENCE

PREDICTION AND PREVENTION OF PRETERM BIRTH RISK

NOVEL PRETRM® GLOBAL TEST
EUROPEAN EXPERTS MEETING



Chairperson:

Gian Carlo Di Renzo, Firenze, Italy



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08:30 - 08:45

Welcome Coffee and introduction
Informal networking

08:45 - 09:00

Welcome at the PREIS School

- Welcome and opening remarks
- Context, objectives, and expected outcomes of the meeting

Gian Carlo Di Renzo

09:00 - 09:30

Session 1 - Sera Prognostics: Company and European Vision

- Introduction to Sera Prognostics and the PreTRM test
- European and international strategy
 - Strategic vision for addressing unmet needs in Europe and beyond
- Progress on the European pathway
 - CE Mark/UK Mark status
 - Laboratory strategy in Europe and LDT considerations
 - Potential European environment introduction pathways

Sera Representatives: Jay Boniface, Yulia Sidorova

09:30 - 10:15

Session 2 - The Unmet Need: Preterm Birth in Europe

- The clinical and societal burden of preterm birth across Europe
- Recognised gaps in current risk identification approaches
- Limitations of existing screening and the need for innovation

Dilly Anumba

- The neonatologist's perspective: impact on neonatal care and outcomes

Umberto Simeoni

- The patient and family perspective: insights from PRERARE and GFCNI

Gian Carlo Di Renzo

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10:15- 10:30

Q&A

10:30-10:50

Break

10.50-11.50

Session 3 - PreTRM Test: Scientific and Clinical Evidence

- Scientific validity and biomarker rationale
- Intended use and test performance
- Clinical validity and supporting evidence
- Relevance to European populations and clinical settings

Sera Representatives: Angie Fox, Jay Boniface, Yulia Sidorova

11:50 - 12:10

Session 4 - Expert Discussion: Evidence and Clinical Value

Seeking expert perspectives on test evidence and clinical positioning. Topics for reflection:

- How compelling is the clinical case for PreTRM in addressing the current unmet need?
- Where might PreTRM add most value alongside existing clinical practice?
- Which aspects of the evidence are most meaningful from a clinician's standpoint?
- What additional evidence would further strengthen the clinical case?

Moderators: G.C. Di Renzo, D. Anumba O.C.

12:10 - 13:20

Working lunch

13:20 - 14:25

Session 5 - Roundtable: Pathways for PreTRM in European Practice

Topics for reflection:

- Where might PreTRM fit most naturally within European clinical pathways?
- What key challenges — clinical, operational, or cultural — should be anticipated?
- What would be most important to support confident adoption in your setting?

Moderators: G.C. Di Renzo, D. Anumba O. C.

Country Perspectives: Landscape, Challenges, and Opportunities.

Sharing country-specific insights and identifying common themes:

- Current approaches to preterm birth prediction and prevention
- Regulatory landscape and system-specific considerations
- Reimbursement environment and funding realities
- Readiness and appetite for prognostic innovation

All Panelists

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14:25 - 14:55

Session 6 - Cross-Country Synthesis

Identifying shared themes and divergences:

- Where are common patterns and opportunities emerging?
- Where do national contexts require a tailored approach?

Moderators: Steve Thornton, Daniel Surbek

14:55 - 15:10

Break

15:10 - 16:10

Session 7 - Strategic Priorities & Recommendations 2026–2027

Exploring potential collaborative initiatives:

- Publication and consensus statement opportunities
- Retrospective database analyses in European populations
- Prospective implementation or validation studies
- Hospital or centre-level pilot programmes
- Educational and awareness initiatives

Gian Carlo Di Renzo &

Sera Representative: Yulia Sidorova

16:10 - 16:30

Summary and Next Steps

- Key insights and conclusions from the day
- Agreed priorities and next milestones
- Follow-up actions and continued collaboration

Gian Carlo Di Renzo &

Sera Representative: Jay Boniface

16:30

Close of the Meeting

Chairperson:
Gian Carlo Di Renzo, Firenze, Italy

PURPOSE

Assess the clinical value of the PreTRM Global test and the European strategy for its introduction, considering country-specific healthcare systems and identifying pathways for expert engagement and endorsement.

EXPERTS

Acs Nandor (Budapest, Hungary) Rizzo Giuseppe (Rome, Italy)
Anumba Dilly O.C. (Sheffield, UK) Simeoni Umberto (Lausanne, Switzerland)
Bartha Jose Luis (Madrid, Spain) Stanirowski Pawel (Warsaw, Poland)
Devlieger Roland (Leuven, Belgium) Surbek Daniel (Bern, Switzerland)
Di Renzo Gian Carlo (Florence, Italy) Thornton Steve (London, UK)
Hollwitz Bettina (Hamburg, Germany) Tudisco Riccardo (Calmart, France)

OBSERVERS FROM SERA PROGNOSTICS

Boniface Jay (Chief Scientific Officer)
Fox Angie (VP of Clinical Operations)
Sidorova Yulia (Head of European Project)

SUPPORTED BY AN UNRESTRICTED EDUCATIONAL GRANT FROM:



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The Pregnancy Company®

Location:

Istituto Degli Innocenti, Sala Pocchetti, Piazza SS. Annunziata 12 – Firenze

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Via F. Ferrucci, 49 59100 Prato
Tel 0574 527949
www.partnergraf.it