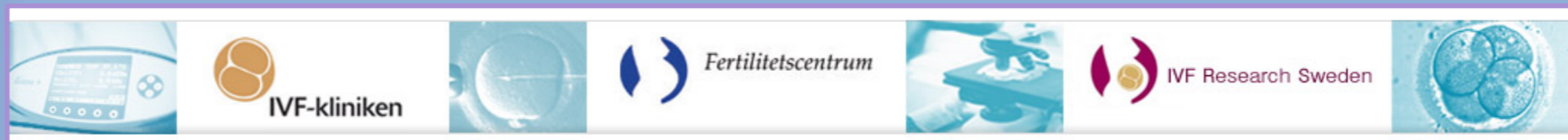




World-wide educational guidelines for clinical embryologists

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Background [1/2]

Constant increases in:

Government regulation of ART, licensing of clinics and of staff

Have revealed that regulatory authorities and professional associations do not always properly recognize the key role of the clinical embryologist, or their roles in effective ART lab direction and management.

Clinical embryologists do not “fit” into any of the traditional categories of lab workers such as technician, technologist or biologist – rather that they are more like “practitioners”.

Background [2/2]

The work of the clinical embryologist is typified by:

- a high degree of technical skill and experience;
- extensive knowledge of many other, non-lab aspects of ART treatment;
- making many of the routine, but crucial, decisions that directly affect patients' treatment

A very different situation to the vast majority of other “medical laboratories” that are directed by a physician who has specialist training in specific areas of laboratory medicine.

Meeting Goals [1/2]

To achieve an international consensus regarding:

Who can / should work as a clinical embryologist?

What are the necessary educational requirements for people who want to become clinical embryologists?

What training is required for someone to work as a clinical embryologist?

What are the necessary competencies required to be able to work as a clinical embryologist?

Meeting Goals [2/2]

As new professional frameworks are developed, how are those already working in the field protected and/or maintain a career path?

How can the profession establish its own guidelines/rules, best practice recommendations, certification, CPD systems for the benefit of its own members (and patients)?

Alpha's over-arching purpose is to establish and expand the minimum requirements for safe and effective ART lab operation, while providing a framework for achieving quality and excellence.

Survey Questionnaires

Managed by the Alpha Office.

34 sent out to national / international societies.

Some countries have >1 society (e.g. Belgium, Turkey, USA, Japan).

Some societies represent more than one country, e.g. SIRT (Australia & New Zealand), NILS (4 Nordic countries + Iceland).

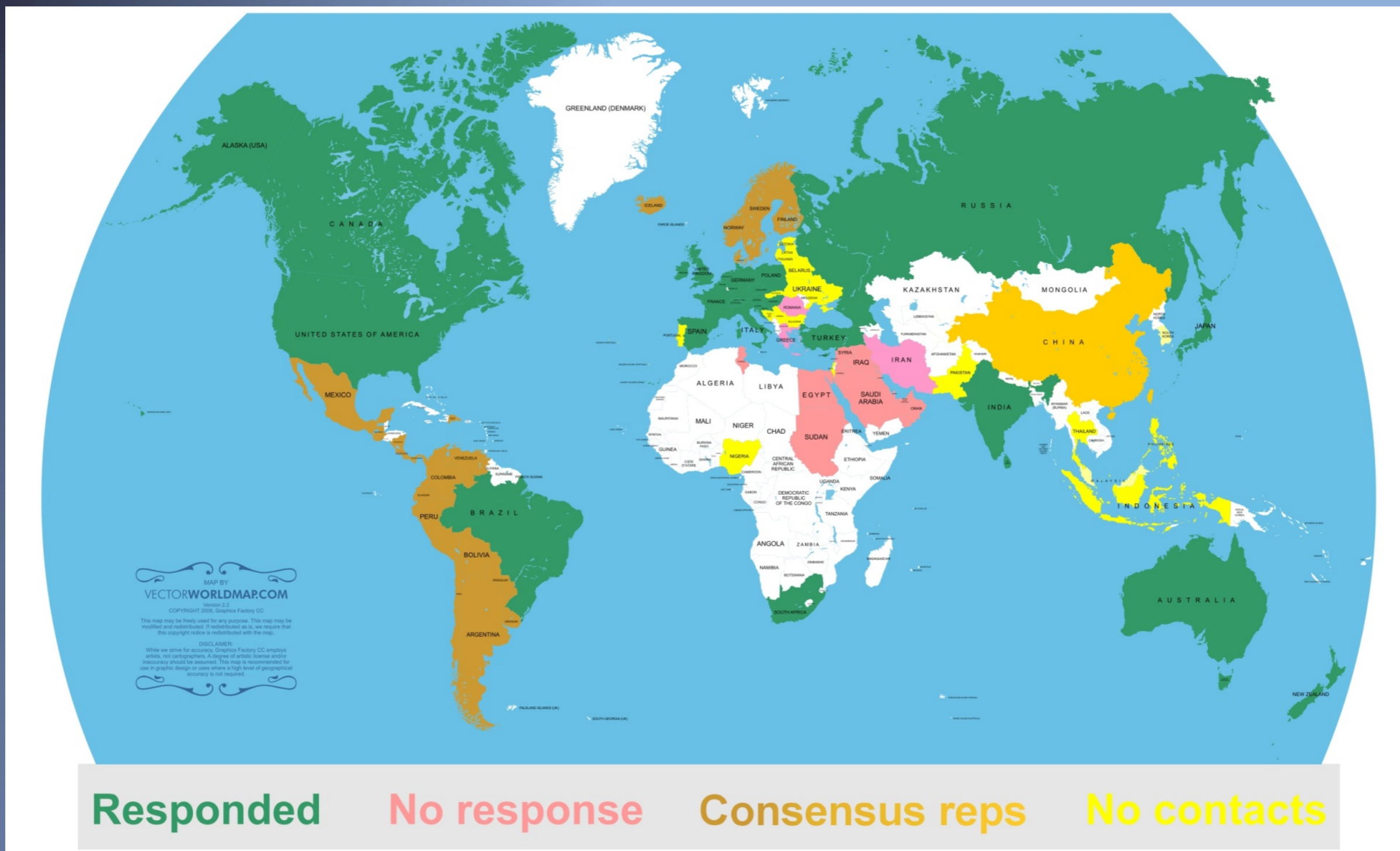
2 large regional / multinational societies: MEFS (Middle East), RED LARA (Latin America).

26 responses received:

Representing actual information from 58 countries.

Submitted regulatory documents often not available in English.

Questionnaire Responses (n=26) and Participation



Consensus Process

Overviews: Summaries of the responses received to the questionnaires sent out by Alpha:

integrating the submitted information;

synthesizing points of commonality or agreement; and

identifying areas of disagreement.

Presentations: Based on the equivalent Overview talk, each acting as a lead-in to the key points for discussion.

General Discussions: Facilitated discussions among ALL the participants to build on the presentations, background material and personal experiences; will be summarized in the Report.

Consensus Discussions: Moderated sessions that build on the interactive discussions to refine the consensus points.

Consensus Report: A formal publication summarizing the meeting and presenting the consensus points, to appear in *RBM Online* by “Alpha Scientists”.

Intent of the Report:

While Alpha is not trying to dictate to regulators, we are certainly seeking to **educate** them.

What makes clinical embryology a special profession.

How we – as professionals – must also protect the interests of infertile patients around the world, and strive towards ensuring they have equitable access to the best possible care and treatment.

Countries / Societies represented

Turkey	Russia
Austria	Scandinavia
USA	Spain
Sweden	Netherlands
Australia	United Kingdom
South Africa	Canada
China	Brazil
Belgium	Italy
Croatia	Ireland
France	Germany

Alpha	RAH
AAB	NILS
SIRT	SASREG
CFS	VVKE
HDKE	BLEFCO
ASEBIR	KLEM
ACE	CFAS
Pronucleo	RED LARA
SIERR	ICE
AGRBM	

Workshop Presentations

Overview Reports on the Survey Responses

- ❖ National Regulations (David Mortimer)
- ❖ Required Academic Qualifications (Joe Conaghan)
- ❖ Training and Education Programmes (Jens Hirchenhain)
- ❖ CPD Requirements (Stephen Harbottle)
- ❖ Roles and Responsibilities (Josep Santalo)

Topic Presentations for Consensus Development

- ❖ Role of the Clinical Embryologist (Ciara Hughes)
- ❖ Educational and Academic Requirements (Ronny Janssens)
- ❖ Training Expectations / Requirements (Nadine Richings)
- ❖ Defining and Assessing Competence (Sharon Mortimer)
- ❖ Continuing Professional Development (Sirpa Makinen)

Consensus on Need

There is a need for an international set of standards for clinical embryologists.

- ❖ Therefore, the aim is to recommend international standards that can be referenced by regulators and Societies around the world.
- ❖ These recommendations are largely “minimum standards”, so they can be exceeded.
- ❖ If there is a disagreement between these recommendations and local/national regulations, then the local/national regulations take precedence.
- ❖ It is the intent that these recommendations should support the development of clinical embryology as a profession, and so should not be used to disenfranchise anyone currently practising.

Consensus on Basic Staffing Structure

The basic staffing structure in the clinical embryology laboratory can be expressed as:

DIRECTION LEVEL

SUPERVISORY LEVEL

EMBRYOLOGIST LEVEL

ASSISTANCE LEVEL

Notes on Basic Staffing Structure

The titles are deliberately generic, since some titles have specific meanings in some countries, which may differ from the meaning in other countries.

The Embryologist level encompasses the continuum of all Embryologists, from trainee through to senior (non-supervisory).

Job descriptions should be tailored to reflect the roles and responsibilities within each position of each laboratory.

In some cases, one person may be required to assume more than one level of the basic structure.

Notes on Roles and Responsibilities

Roles within each staffing level were defined using Ciara Hughes' PACER system of classification.

PACER = Personal, Administration, Clinical, Education, Research

Not all staff members within a particular staffing level will have the same responsibilities – these will depend upon training and competency.

If any role listed in the PACER system disagrees with, or is not appropriate, under local or national regulations, then the local or national regulations take precedence.

PACER system: Research

Assistance level	Support and/or participate in any research activities
Embryologist level	Propose and/or participate in clinical research studies
Supervisory level	Propose, participate in, and/or implement clinical research studies
Direction level	<ul style="list-style-type: none">• Initiate, design, and implement research studies (including obtaining ethical approval) and follow through with an analysis and publication.• Capable of applying for funding, grants, etc., and collaborating with external institutions.

Consensus on Entry Level Qualifications

Assistance level: BSc or equivalent technical qualification.

Embryologist level: BSc or equivalent academic or technical qualification.

Supervisory level: Ideally MSc, but BSc at a minimum*; as well as 5 years' clinical embryology laboratory experience.

Direction level: Ideally, earned doctorate in biomedical science , but MSc at a minimum.

Also, at least 5 years' experience for those with a doctorate or at least 10 years' experience for those with an MSc.

** This was not a unanimous decision, as some countries have legislated higher standards for lab supervisors*

Notes on Entry Level Qualifications

The recommended educational qualifications represent the minimum standard for entry into each level of clinical embryology.

Having a higher educational qualification than the recommended minimum standard should not be a reason for disqualifying a clinical embryologist candidate.

In cases where these minimum standards are superseded by national regulations, the national regulations take precedence.

If someone is currently working in a position that has a higher recommended entry level qualification than they possess, a “grandfathering” clause should be applied to confirm them in that position, based on experience and competency.

Consensus on Staffing Levels

The recommended staffing levels for a clinical embryology laboratory are one FTE “bench” or “hands-on” embryologist per 120 stimulation cycles per year.

Consensus on Education and Training

Alpha recognizes a need for a curriculum outline to facilitate the education of clinical embryologists throughout their career development.

Progression to the next level of clinical embryologist (i.e. to supervisor then to director) should be subject to the successful completion of the educational requirements for that level.

The framework [to be] presented is seen as a “gold standard”.

It is the consensus that theoretical knowledge should be examined.

The sections and topics of the Clinical Embryology curriculum

	EMB 1	EMB 2	EMB 3
Biology & ART			
1: Biology	1.1:	2.1:	3.1:
2: Technology: Theoretical	1.2:	2.2:	3.2:
3: Technology: Practical	1.3:	2.3:	3.3:
A Broader Perspective: Outcome, Quality, Safety & Risk			
4: Monitoring Outcome & Quality	1.4:	2.4:	3.4:
5: Safety & Risk	1.5:	2.5:	3.5:
6: Other Professions & Roles in ART	1.6:	2.6:	3.6:
More than Science: Administration, Documentation & Liaison			
7: Legislation & Regulation	1.7:	2.7:	3.7:
8: Communication, Information & Accuracy	1.8:	2.8:	3.8:
9: Personal Skills & Attributes	1.9:	2.9:	3.9:
Advancing Your Career			
10: CPD	1.10:	2.10:	3.10:
11: Research & Scientific Principles		2.11:	3.11:
12: Management Training			3.12:

Consensus on Defining and Assessing Competence

- Each lab should use a competency framework to define each aspect of the task and how the individual is assessed.
- Logbooks should be competency-based rather than activity-based.
- Each Lab Director should set KPIs and benchmarks for their lab.
- Competence is defined by the achievement of the KPI control ranges for the outcome, and is maintained over the average of at least 10 typical cases.
- Maintenance of competence is assessed at least annually, using the same method as for assessing achievement of competence.
- Maintenance of competence will be harder in clinics with low numbers of cycles per year.

Consensus on Continuing Professional Development (CPD)

- It is a professional obligation of all clinical embryologists to participate in CPD activities
- For Lab Directors, active participation in CPD activities is mandatory.
- All clinical embryologists must be given the opportunity to participate in CPD activities.
- Any licensing or certification scheme of clinical embryologists must include a requirement for ongoing CPD.

Support for this meeting was provided by:

Ferring Pharmaceuticals

Vitrolife

IBSA

Fertilitech

Gynemed

National Clinical Embryology and Fertility
Societies

Accepted for publication in RBMOnline

The Alpha Consensus meeting on The Professional Status of the Clinical Embryologist: Proceedings of an expert Meeting directed by Alpha

Author: Alpha Scientists in Reproductive Medicine

Participants (in alphabetical order): Jose Roberto Alegretti¹, Başak Balaban²⁻²⁰, Joe Conaghan³, Mariabeatrice Dal Canto⁴, Thomas Ebner², Bart C. Fauser², David Gardner², Jean-Francois Guerin⁵, Stephen Harbottle⁶, Thorir Hardarson², Jens Hirchenhain⁷, Guoning Huang⁸, Ciara Hughes⁹, Ronny Janssens¹⁰, Lev Levkov¹¹, Dejan Ljiljak¹², Sirpa Mäkinen¹³, Debbie Montjean⁵, David Mortimer¹⁴, Sharon Mortimer¹⁵, Zsolt Peter Nagy², Nadine Richings¹⁶, Josep Santalo Pedro¹⁷, Zhengyi Sun⁸, Marie-Lena Windt de Beer¹⁸, Yvonne Wurth¹⁹

human
reproduction

ORIGINAL ARTICLE ESHRE pages

The Istanbul consensus workshop on embryo assessment: proceedings of an expert meeting[†]

**Alpha Scientists in Reproductive Medicine and ESHRE Special
Interest Group of Embryology**

ELSEVIER

ARTICLE

**The Alpha consensus meeting on cryopreservation
key performance indicators and benchmarks:
proceedings of an expert meeting**



Summarizing

There is a need for comparable standards across the world for people working in clinical embryology.

A standardized training program will be developed to achieve this aim

Alpha, as a global international society, is the natural Society to develop such a program

Will include both a knowledge component (providing education in areas relevant to the embryologist), and a practical component (following a competency-based training and evaluation model).





ALPHA 2016

11th Biennial Conference

05-08 May, 2016
Radisson Blu Scandinavia Hotel
Copenhagen, Denmark



1st Announcement

www.alphaconference2016.org

11th Biennial Conference

ALPHA 2016

Scientists in Reproductive Medicine



Scientific Program

6 May 2016, Friday

07.30 - 09.00 Registration

SESSION 1

Gamete Maturation

- 09.00 - 09.20 Oocyte-cumulus signalling; challenging how we perceive the oocyte
Tom Adriaenssens (Belgium)
- 09.20 - 09.40 Clinical use of IVF; is this really only for PCOS patients?
Yoshiharu Morimoto (Japan)
- 09.40 - 10.00 Contribution of the male gamete to embryo development: How can we select the best sperm?
Ashok Agarwal (USA)

10.00 - 10.15 Discussion

10.15 - 10.45 Coffee break ☕

10.45 - 11.45 Satellite Symposium 1

SESSION 2

The exquisite dialogue between mother and embryo; Implantation

- 11.45 - 12.15 Keynote lecture 1 The receptive endometrium, the dialogue begins
Nick Macklon (UK)
- 12:15 - 12.45 Keynote Lecture 2 Signals from the embryo
Sudhansu K. Dey (USA)

12.45-13.45 Lunch 🍴

13.45- 14.45 Satellite Symposium 2

SESSION 3

Embryo Culture in the 21st Century

- 14.45 - 15.05 The media we use; what's in them and why
David K Gardner (Australia)
- 15.05 - 15.25 Metabolic heterogeneity of the human embryo
Daniel Brison (UK)
- 15.25 - 15.35 Discussion
- 15.35 - 16.20 Free Communications Session
- 15.35 - 15.50 FC 1
- 15.50 - 16.05 FC 2
- 16.05 - 16.20 FC 3
- 16.20 - 17.30 GM (General Assembly)

19.00 - 21.00 Visual Art Show & Welcome Cocktail

11th Biennial Conference

ALPHA 2016

Scientists in Reproductive Medicine



7 May 2016, Saturday

SESSION 4

Selection of the viable euploid embryo

- 09.00 - 09.20 Morphokinetics and Biomarkers
Kirstine Kirkegaard (Denmark)
- 09.20 - 09.40 SNP, CGH and Next Gen
Dagan Wells (UK)
- 09.40 - 10.00 Do we really need embryo selection?
Sebastian Mastenbroek (The Netherlands)

10.00 - 10.15 Discussion

10.15 - 10.45 Coffee Break ☕

10.45 - 11.45 Satellite Symposium 3

SESSION 5

"The Danish Session"

- 11.45 - 12.05 Syncytin – the protein mediating the fusion of egg and sperm membrane?
Morten Rønn Petersen (Denmark)
- 12.05 - 12.25 From monoovulator to polyovulator – impact on oocyte quality
Fieneke Lemmen (Denmark)
- 12.25 - 12.45 Egg and Age - impact of female age on oocyte and embryo assessment parameters
Marie Louise Grøndahl (Denmark)

12.45-13.00 Discussion

13.00-14.00 Lunch 🍴

14.00-15.00 Satellite Symposium 4

SESSION 6

New technologies in ART

- 15:00 - 15:30 Keynote lecture 3 Analysis of miRNA
Antonio Capalbo (Italy)
- 15:30 - 16:00 Keynote lecture 4 Artificial gametes
Jerry Schatten (USA)

16.00-16.30 Coffee break ☕

PACER **system: Personal**

<p>Assistance level</p>	<ul style="list-style-type: none"> • Apply ethics and integrity, critical thinking, good communication within the team, time management and team work skills. • Active participation in QMS
<p>Embryologist level</p>	<p>As for Assistance level as well as: Ability to communicate effectively</p>
<p>Supervisory level</p>	<p>As for Embryologist level as well as: Ability to teach and train effectively</p>
<p>Direction level</p>	<p>As for Supervisory level as well as:</p> <ul style="list-style-type: none"> • Ability to manage, lead and motivate staff. • Develops and maintains relationships with other professionals within the field

PACER system: Administration

Assistance level	Record-keeping and adherence to SOPs
Embryologist level	As for Assistance level as well as: Cryobank operation
Supervisory level	As for Embryologist level as well as: <ul style="list-style-type: none"> • Coordinating the transport of gametes and embryos between centres. • Managing Change Control
Direction level	<ul style="list-style-type: none"> • Overall responsibility for all aspects of laboratory management. • Compliance with local legislation • Maintaining authorisation to practice / license • Operating the service within budget • Resource management • Ensuring all job descriptions are up to date and accurate • Ensuring service level agreements are in place with all critical suppliers • Authorising and implementing changes to SOPs. • Delegation of tasks

PACER system: Clinical (1)

<p>Assistance level</p>	<ul style="list-style-type: none"> • Support of laboratory operations and environmental QC • Adherence to clinic policies and SOPs
<p>Embryologist level</p>	<ul style="list-style-type: none"> • Semen analysis, semen preparation, sperm diagnostic tests (performed to appropriate standards) • Adhering to clinic policies and SOPs. • Ensuring all equipment is functioning properly. • All gamete and embryo handling and assessment • All gamete and embryo cryopreservation • Generating Clinical Key Performance indicators for review (KPIs) • Adopting clinical decisions. • Adhering to patient consents

PACER system: Clinical (2)

Supervisory level

As for Embryologist level as well as:

- Act as the Deputy Laboratory Manager
- Participate in clinical reviews and make decisions
- Review and act on KPIs
- Process validation
- Supervise and train junior staff
- Ensure competency of staff working in the lab.
- Introduce new technologies / methods
- Ensure SOPs are adhered to
- Participate in scheduling of cycles / cycle management
- Ensuring all equipment is properly maintained

PACER system: Clinical (2)

Direction level

As for Supervisory level as well as being ultimately responsible for:

- Ensuring that the laboratory is 'fit for purpose' in terms of security, space and cleanliness and with adequate equipment.
- Ensuring that SOPs and policies are up to date and accurate, according to international best practice
- Developing and reviewing KPIs, benchmarks, dealing with any deviances
- Ensuring an adequate number of competent staff to cover case load
- Ensuring that staff have meetings within their own department and are encouraged to attend case and clinical review meetings
- Authorizing the introduction of any new technique.
- An effective quality management system within the laboratory

PACER system: Education

Assistance level	Keep up to date with education, training, and competency.
Embryologist level	<p>As for Assistance level as well as:</p> <ul style="list-style-type: none"> • Keep up to date with new guidelines, and diagnostic or therapeutic technologies. • Participates in CPD. • Participates in training of trainees
Supervisory level	<p>As for Embryologist level as well as:</p> <ul style="list-style-type: none"> • Supervise and train junior staff
Direction level	<p>As for Supervisory level as well as:</p> <ul style="list-style-type: none"> • Ensure that new staff have a comprehensive training plan or are enrolled in a certification scheme (ACE, ESHRE ...) with ongoing competency assessments. • Ensure that all staff have the opportunity to participate in CPD. • Encourage and aim to fund, attendance at training courses, conferences, post graduate courses. • Ensure that their own CPD, training and competency is up-to date. • Staff appraisals.