

ESHRE certificaat voor embryologen en ART centra?

Kwaliteitsmiddag KLEM

11 juni 2019

Dr. L. Ramos

Radboudumc & lid van de Steering Committee Clinical Certification ESHRE

No conflict of interest

**Actief lid van de *EmCC Steering Committee*
sinds 2016**

**Alle informatie is te vinden op de website van
ESHRE- *slides van ESHRE met toestemming***

ESHRE certification for embryologists



ART Centre Certification for good clinical practice



Radboudumc

EmCC Steering Committee



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Declaration of interest



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Established to define a scheme for certification of clinical embryologists & develop a formal recognition for embryologists

Works in close collaboration with the Executive Committee & SIG-Embryology

From February 2019, 2 new members: Daniela Noriega (Fr) and Giovanna Tomasi (It)

Wat is U.E.M.S-CESMA?



UNION EUROPÉENNE DES MÉDECINS SPÉCIALISTES
EUROPEAN UNION OF MEDICAL SPECIALISTS

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**Areas of
Expertise**

CME - CPD

**Postgraduate
Training**

The Council for European Specialists Medical Assessment

The CESMA is an advisory body of the UEMS created in 2007 with an aim to provide recommendation and advice on the organisation of European examinations for medical specialists at the European level.

The ESHRE Embryology Certification exam has now received formal recognition from CESMA (Council for European Specialist Medical Assessment)

ESHRE certification

Clinical Embryologist	Senior Clinical Embryologist
be an ESHRE member , click here for more information on ESHRE membership	
hold a BSc in Natural Sciences	hold a MSc or PhD in Natural Sciences
have at least three years' hands-on experience with human gametes and embryos in a clinical ART lab (at the time of the application deadline)	have at least six years' hands-on experience with human gametes and embryos in a clinical ART lab (at the time of the application deadline)
submit a valid logbook (please see rule #3.10 logbook requirements) showing the required hands-on experience	

Waarom ESHRE certification?

Embryologists require a foundation to:

- prepare for & adapt to the new technologies
- understand the relevance & application of advances in cell biology & genetics
- apply good clinical practice

Embryologists achieving high professional standards can now obtain certification to demonstrate their level of expertise & knowledge.

The system provides 2 levels of certification: one for **senior** level clinical embryologists and one for **clinical** embryologists

Information for applicants

- XX Oct – XX Dec: Online applications accepted
- Feb: Applicants informed if they have been accepted
- May: Applicants receive confirmation & seat number
- July: Exam on Saturday before ESHRE meeting

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[Links](#)
[Certification platform](#)
[Frequency of scores Geneva 2017](#)
[? Frequently asked questions](#)

Information for exam applicants

The applications for the exam in 2018 will be available online from **18 October until 15 December 2017** (or until maximum capacity is reached). In January and February all submitted applications will be reviewed by the Embryology Certification Steering Committee. By end of February all applicants will be informed whether or not their application has been accepted to sit for the exam. The next exam will be held in **Barcelona, Spain** on **Saturday 30/06/2018** (15:00-17:15)

For the 2018 embryology exam, ESHRE will start with a pilot project on the organisation of a long distance e-exam allowing 40 embryologists **working outside of Europe** to take the exam online at the AILSG centre in New Delhi, India. The participants in New Delhi will have to complete the exam on a computer and they will start at the same time as the participants sitting the paper exam in Barcelona. Applicants who select 'New Delhi' as the exam location will **not** be able to change to Barcelona (or vice versa) after being accepted.

Before end of May all accepted participants will receive a confirmation letter with their seat number. Participants need to bring this confirmation letter to the Exam badge pick up desk on Saturday 30 June. The desk will open at 10h00 but will transform into a cash desk at 13h00. It is therefore recommended to **pick up the exam badge between 10h00 and 13h00** in order to avoid long queues. Participants without an exam badge will not be admitted to the exam room.

Curriculum

Applicants will be expected to have a good knowledge of the following aspects of clinical embryology.

[Read here](#)

Literature list

Suggested reading list

[View here](#)

Model exams

-> Clinical Embryology
-> Senior Embryologists

[View here](#)

Information for applicants

- Literature list

Suggested Reading List

Last update 13 October 2017

Main list

- Human Embryology & Developmental Biology, 2013
Bruce Carlson
- Essential Reproduction (6th edn) Johnson, M (2007), Blackwell Scientific
- In vitro fertilization (3rd edition)
Elder and Dale, Cambridge University Press, 2011

- Digital Exams from 2019: 2 types of questions
(single best answer & Multiple best answers)

Sample exam Senior

Questions with a single best answer only:

1. *According to the European Directive 2012/39/EU and as far as partner donation of reproductive cells is concerned, the permitted time interval until repeat blood testing is:*
 - a) Up to 24 months
 - b) Every 6 months
 - c) Every time the samples are produced
 - d) Up to 12 months
 - e) Every time the samples are used

Logbook - Minimum No. of Procedures Required

1. Oocyte pick-up
2. Semen analysis
3. Semen preparation
4. IVF insemination
5. ICSI
6. Zygote & embryo evaluation
7. Embryo transfer
8. Cryopreservation of oocytes/embryos
9. Thawing/warming of oocytes/embryos

Min. 50
for each

All 9 procedures must be included
in your logbook- currently active in at least 5 areas

Logbook & Work Experience

- Logbook should state how many cycles you performed
- Include start & end dates of performance of each of the 9 procedures
- At least 3 years (clinical) /6 years (senior clinical) is required for at least 5 out of 9 procedures.
- If you changed clinic, a separate logbook should be sent from each clinic, verified & signed by the respective lab supervisor

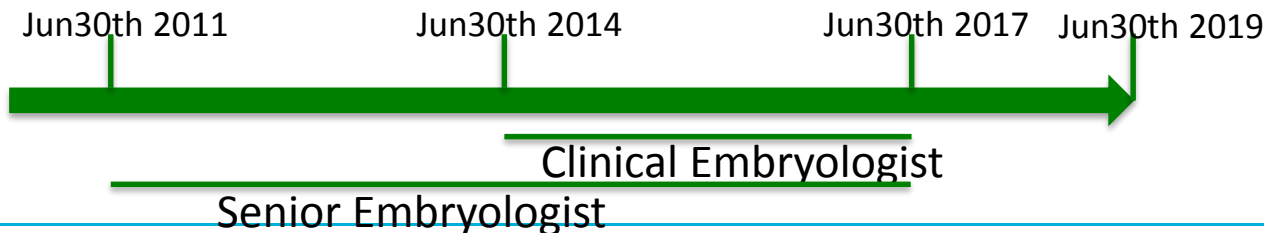
Submission of incorrect information will lead to application rejection, make invalid any previous certification issued by ESHRE & eventually exclusion from ESHRE

Logbook & Work Experience

- Supervisors should be different from your references
- All application details & logbooks may be verified with the supervisors & references

Applicants no longer working as embryologists can apply, provided they worked for at least 3 or 6 years according to their intended application, and ended their last position no longer than 2 years before the exam date

(see example below)



How to fill in a Logbook

Clinic: ..

Type of Procedure	Start date	Stop date	Total number of clinical cycles performed by yourself since the start of your employment in this clinic	Total number of clinical cycles performed in the clinic (by yourself and others) in 2017 only
Oocyte pick up	June 2009	Still ongoing	577	124
Semen analysis	June 2009	Still ongoing	750	709
Semen preparation	June 2009	Still ongoing	726	121
IVF insemination	June 2009	Still ongoing	61	45
ICSI	August 2013	Still ongoing	63	220
Zygote and embryo evaluation	June 2009	Still ongoing	1330	1465
Embryo transfers	June 2009	Still ongoing	584	930
Cryopreservation of oocytes / embryos	February 2010	Still ongoing	155	311
Thawing / warming of oocytes / embryos	May 2010	Still ongoing	366	663
Signature applicant			Signature supervisor	

Exam Rules

Pass level = at least 66/100 correct answers

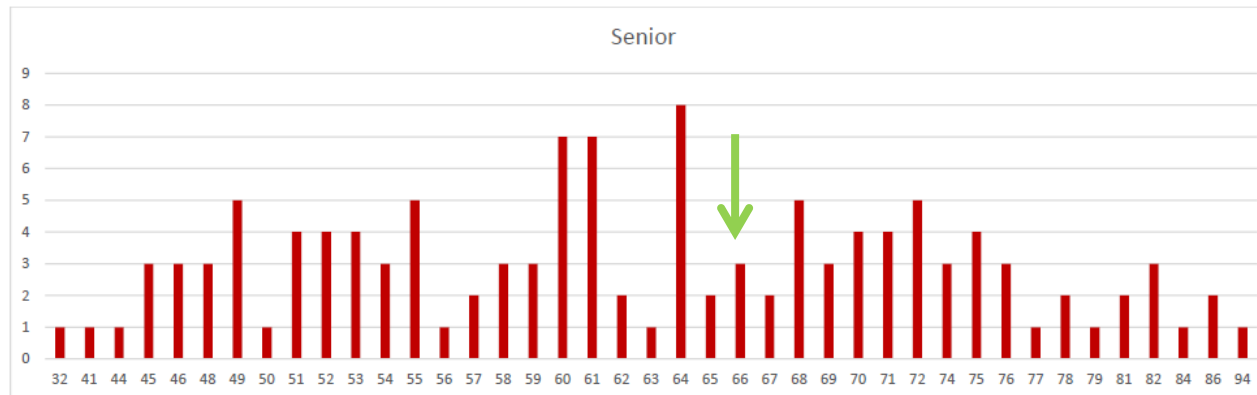
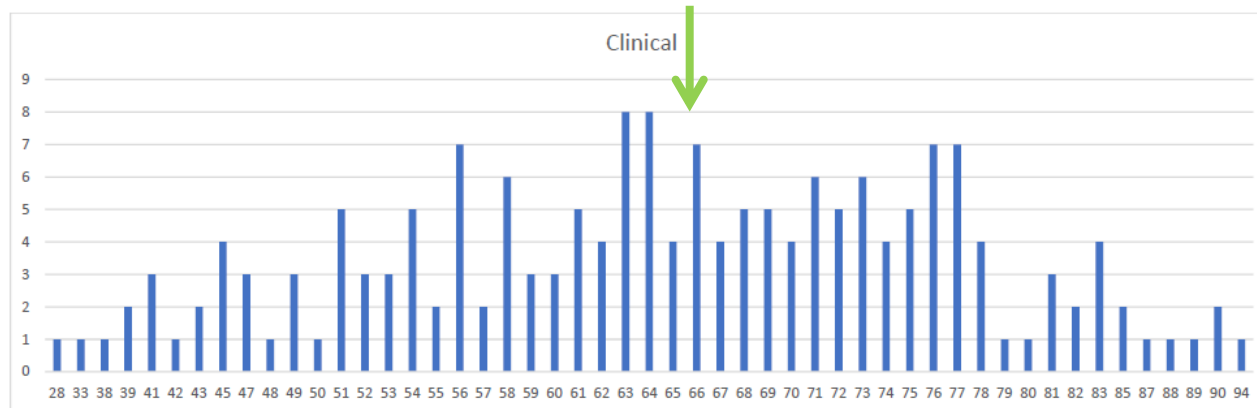
- Exam questions represent intellectual property.
- Due to the risk of abuse, applicants cannot see the exam paper/log by special link
- Applicants can have 3 consecutive attempts at sitting the exam
 - this includes non-attendance of exams if place allocated
- Applicants cannot switch to another exam level on the day

The decision of the Executive Committee is final

Resultaten 2018

FREQUENCY OF SCORES Embryology exams 30 June 2018

Horizontal axis: exam marks - Vertical axis: number of participants which scored that mark



ESHRE-CPD

Continuous Professional Development



ESHRE-CPD Credit System

To encourage ESHRE Certified Senior & Clinical Embryologists to stay updated on the field of embryology & assisted conception & record their CPD activities.

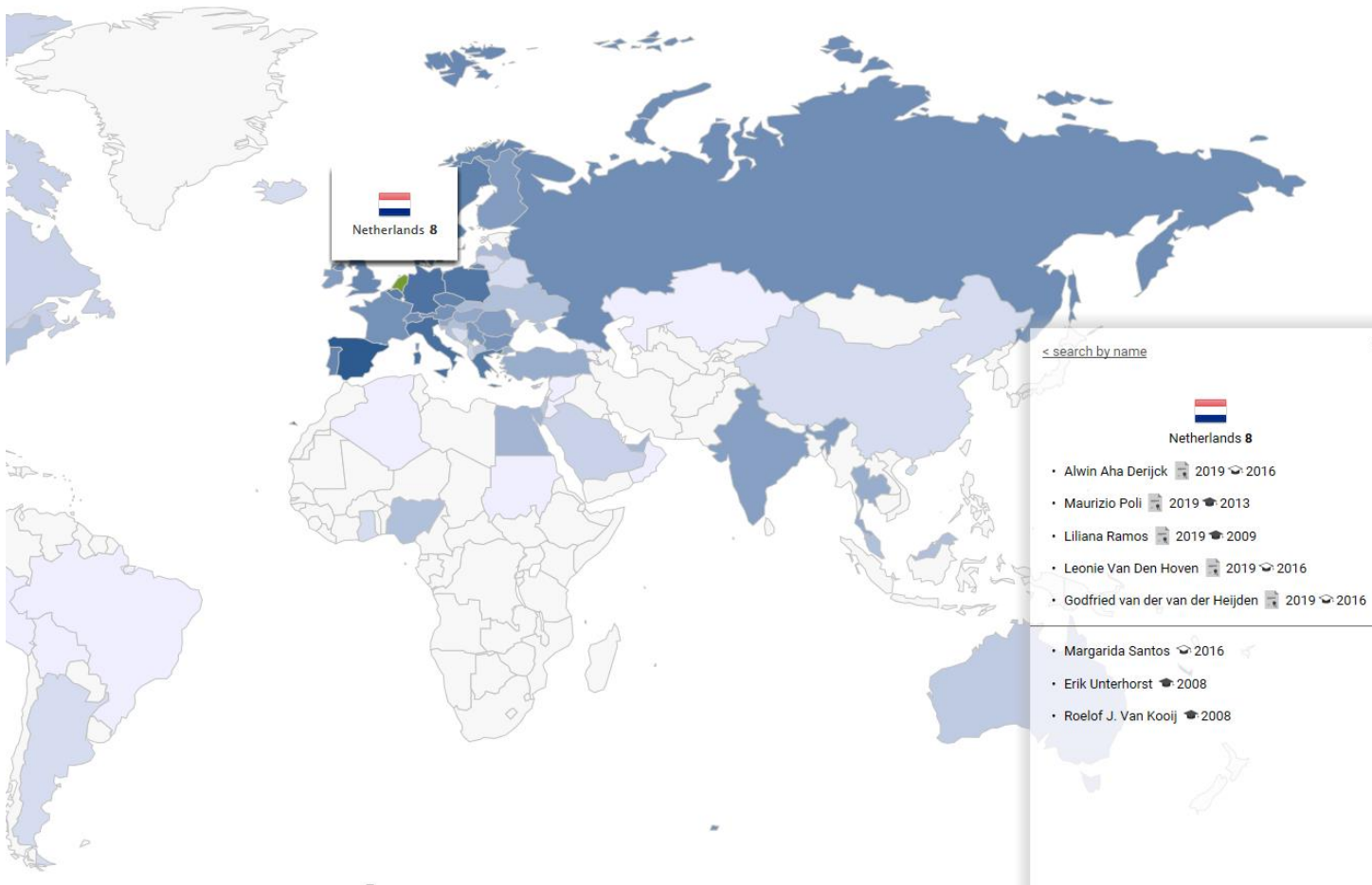
How does it work?

Must collect at least 60 credits (clinical embryologists) or 100 credits (senior embryologists) over a 3yr period, with a minimum of 10 credits in the immediate past year.

To obtain a CPD certificate, participants must also submit a CPD logbook of their lab activities from the past year, showing that at least one category of procedures was performed.

<https://www.eshre.eu/Accreditation-and-Certification/Certification-for-embryologists>

All ESHRE certified embryologists per country



ART Centre Certification for good clinical practice

ART CENTRE CERTIFICATION FOR GOOD CLINICAL PRACTICE



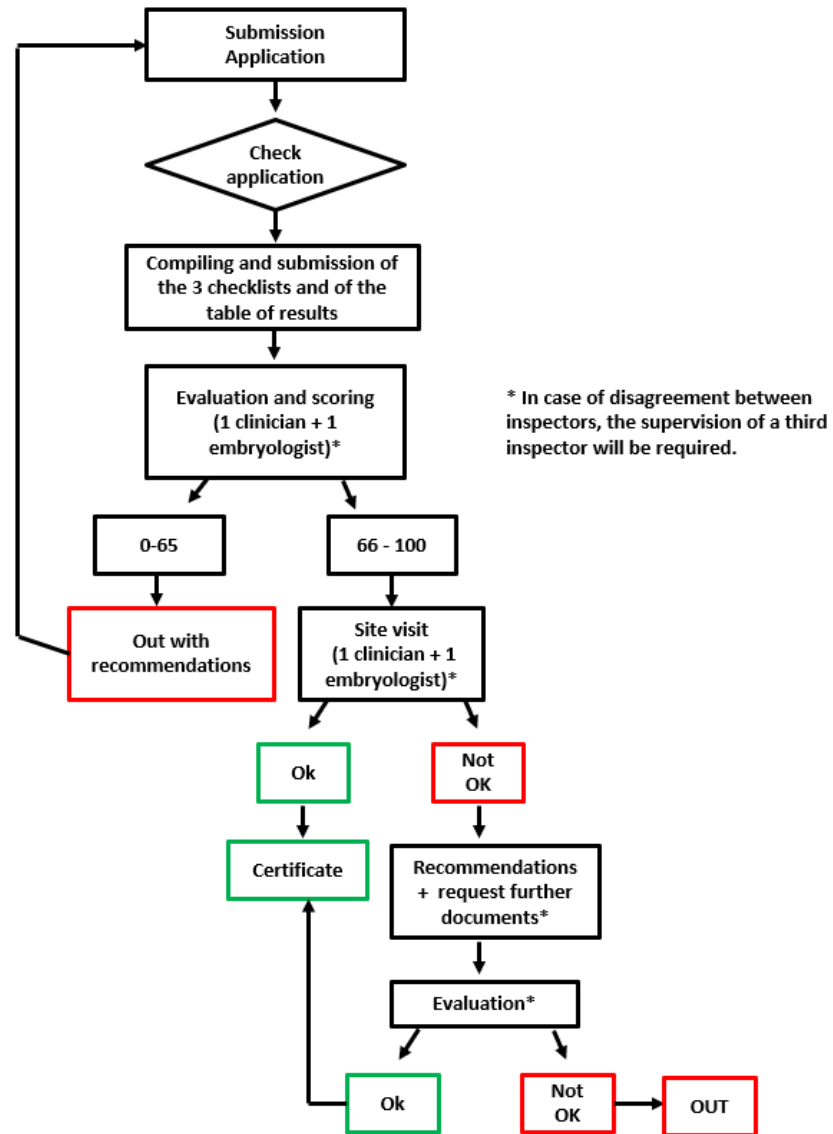
Radboudumc

Waarom de ESHRE-ART Center Certification (ARTCC)?

1. Evalueert kliniek en lab, “Total Quality Management”
2. Bevordert een continue verbetering en stimuleert “best practice”
3. Quality Assessment: de gecertificeerde centra worden zichtbaar voor patiënten, professionals en evt andere instanties.
4. Gecertificeerde centra zullen voordeel hebben van:
 - ☐ Internationaal erkenning (“Certificate of Good Medical Practice”)
 - ☐ Gereduceerde tarief voor members voor andere ESHRE certificates en ESHRE activiteiten (workshops, congressen, etc)
 - ☐ Publicatie op de ESHRE webpage/ Fertility Europe webpage
 - ☐ Toegang tot the Annual meeting voor gecertificeerde centra
 - ☐ Plaatsing in the prioriteiten lijst voor Multi-center trials

Hoe werkt het?

(zie ook ESHRE website)



De checklist

Checklist general services:

Authorizations
Personnel
Building & infrastructure
Training and education
Work organization and responsibilities
Quality management
Protective measures for patients and staff
Patient information

Checklist laboratory services:

Staffing and direction in laboratory – qualifications
Workload
Laboratory design
Laboratory cleaning
Equipment
Consumables
Protective measures
Handling of biological material
Oocyte collection
Semen analysis
Sperm preparation
Insemination of oocytes
Fertilization, embryo culture and transfer
Cryopreservation
Embryo biopsy
Genetic diagnosis
Quality management
Transportation of biological material

Checklist clinical services

Staffing and direction – qualifications
Workload
Clinical design
Operating room (OR) cleaning
Equipment
Consumables
Protective measures
Patient informed consent
Oocyte retrieval
Fertilization, embryo culture and transfer
Quality management
Possibility of surgery
Donor recruitment (if applicable)
Psychology
Nursing

Checklist treatments, pregnancies and deliveries

ESHRE IVF clinical outcomes through IVF, ICSI, Cryopreservation, Oocyte donation, PGT:

Clinical pregnancies per aspiration (%)
Multiple pregnancies (%)
Abortions (%)
Induced fetal reductions (n)
Deliveries per aspirations (%)
Deliveries per ETs (%)
Twins (%)
Triplets (%)

Number of treatments, pregnancies and deliveries (for cycles with women's own oocytes)

Initiated cycles
Aspirations
Freeze all, oocytes
Freeze all, embryos
Transfers
Pregnancies, total
Deliveries
Pregnancies with unknown outcome

Mogelijk voordelen van *ESHRE certification programme*...

(Senior) Clinical embryologist

- Volledige theoretische toetsing, aanvullend aan onze eigen opleiding
- UEMS-CEMA erkenning
- Europees erkenning van ons beroep>> *voordeel bij een evt BIG registratie?*
(in Zwitserland is verplicht voor het beoefenen van werk als embryoloog)

Mogelijk voordelen van *ESHRE certification programme*...

ART center certification

- Speciaal voor ART, auditoren zijn gynaecologen en senior embryologen
- Vervanging van ISO9001/15189
- Lab en Kliniek worden gecertificeerd, stimuleert samenwerking
- 1 x per 3 jaar een visitatie
- Lagere kosten dan RvA
- Internationaal zichtbaarheid (website van ESHRE)

Kan deze 3 jaarlijks bezoek gezien worden als “visitatie”?

Wie overweegt de ESHRE Senior certification te doen? En ESHRE ARTCC aan te vragen?



VERENIGING VOOR
KLINISCHE EMBRYOLOGIE