

In vitro fertilization with personalized blastocyst transfer versus frozen or fresh blastocyst transfer: a multicenter, randomized clinical trial

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Disclosure

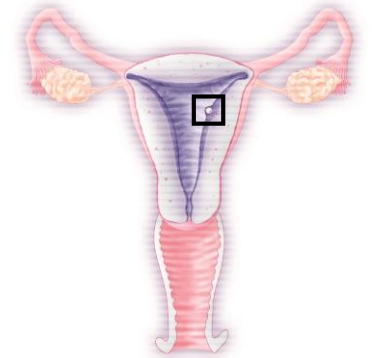
> Founder & Head of Scientific Advisory Board, Igenomix, S.L.

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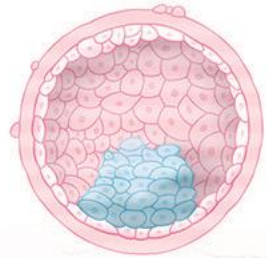
These data were presented in the last ASRM Congress. With this presentation, we want to show you the data obtained with the ERARCT study. Please, don't share this presentation without previous authorization.



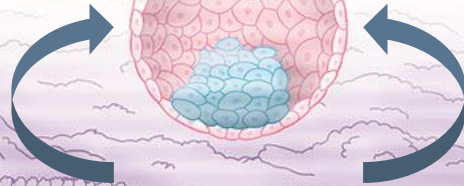
The Endometrial Factor in ART



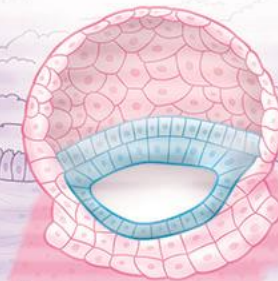
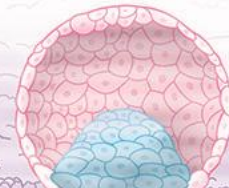
Maternal-Embryonic Crosstalk



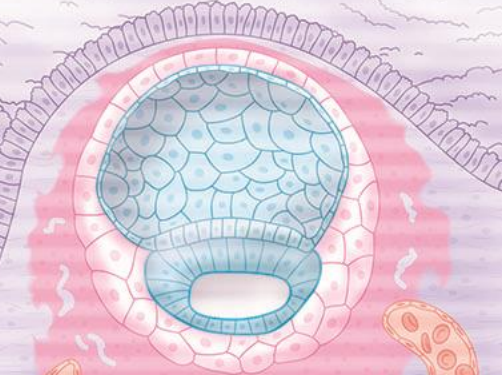
Endometrial
Microbiota



Endometrial Receptivity



Decidualization



Decidualization

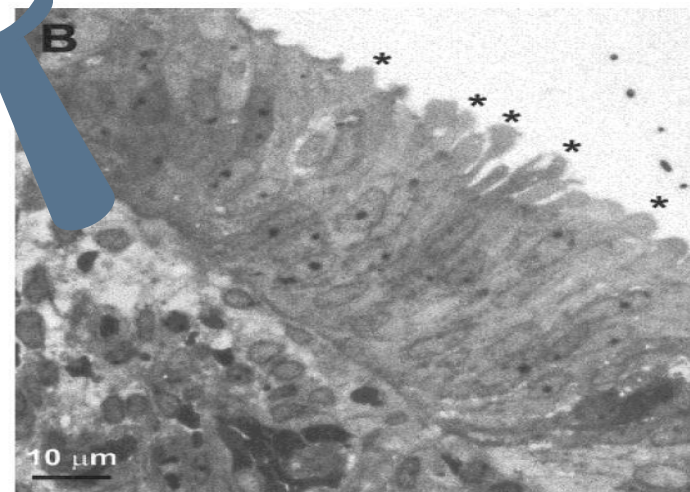
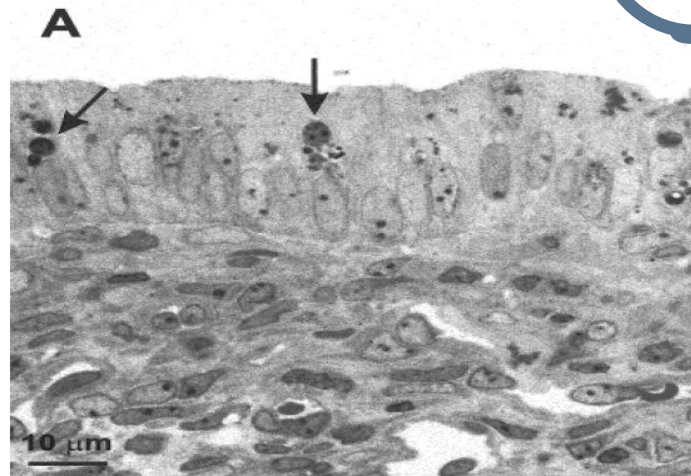
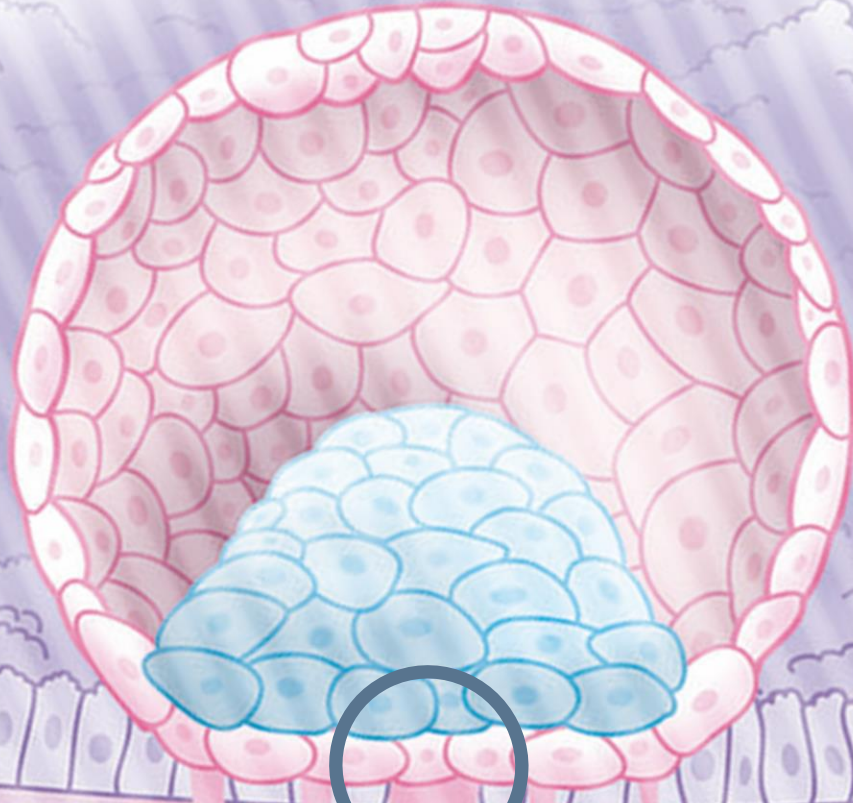
Moreno et, al. AJOG 2016
Moreno et, al. AJOG 2018

Vilella et, al. Development 2015
Balaguer et, al. MHR 2018
Balaguer et, al. AJOG 2019

Díaz-Gimeno et, al. F&S 2011
Ruiz-Alonso et, al. F&S 2013
Garrido-Gomez et, al. HR 2014
Von Grothusen et, al. HR 2018
Wang W. et al. Nature Medicine. 2019 in press
Simon C. et al. HR 2019 submitted

Garrido-Gomez et, al. JCEM 2011
Garrido-Gomez et, al. Development 2017
Garrido-Gomez et, al. PNAS 2017

Endometrial receptivity



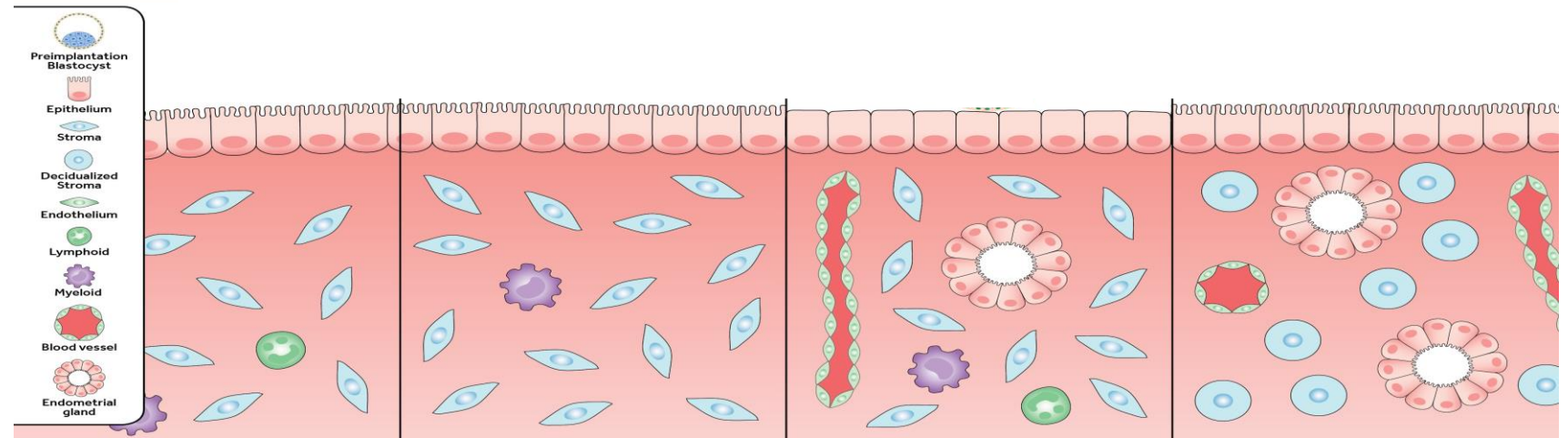
Plasma membrane transformation

Molecular medicine: human endometrial transcriptome

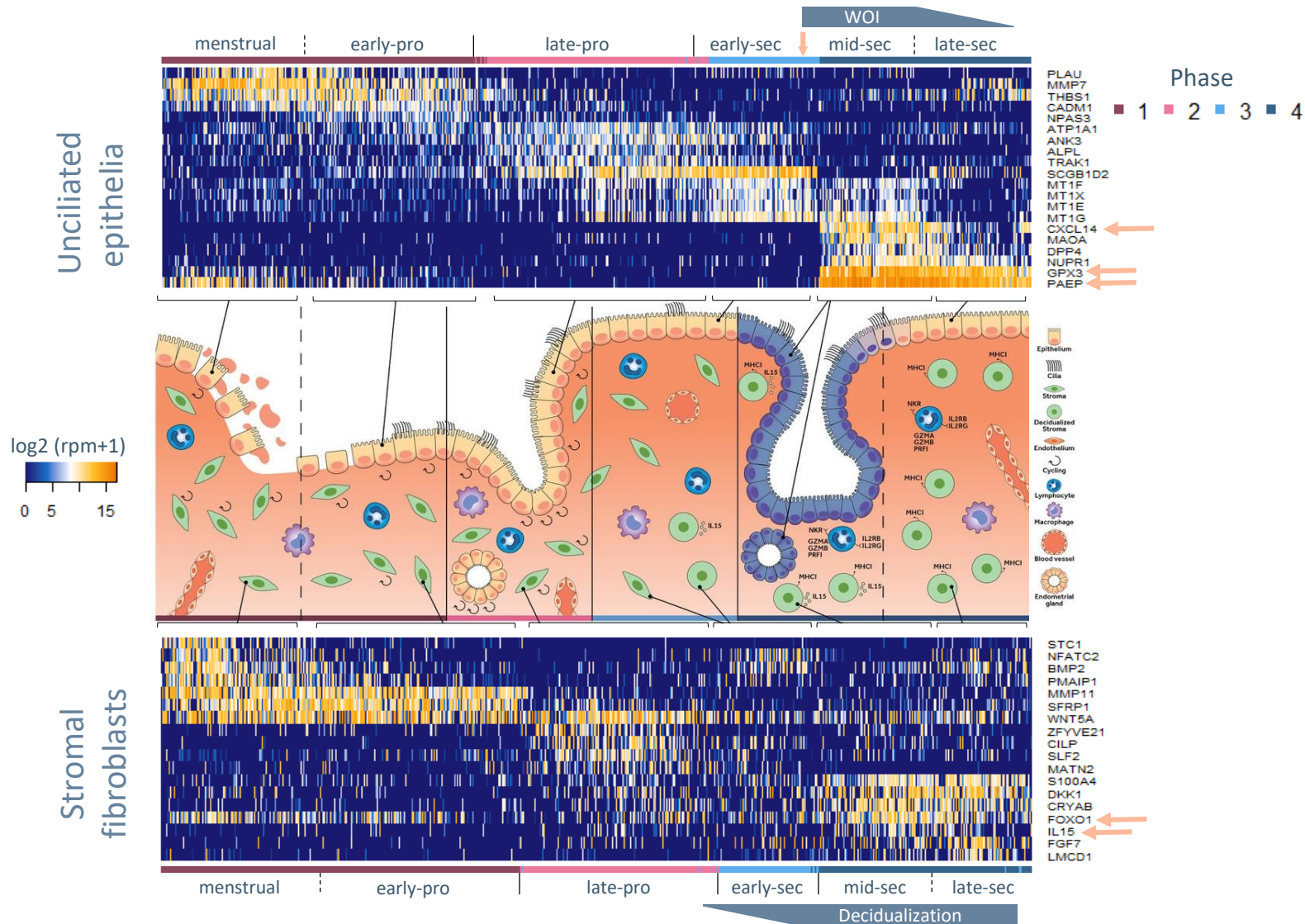
Riesewijk et al., 2003 (HG-U133 2.0) WOI

Ponnalam et al., 2004 (Home-made array) menstrual cycle

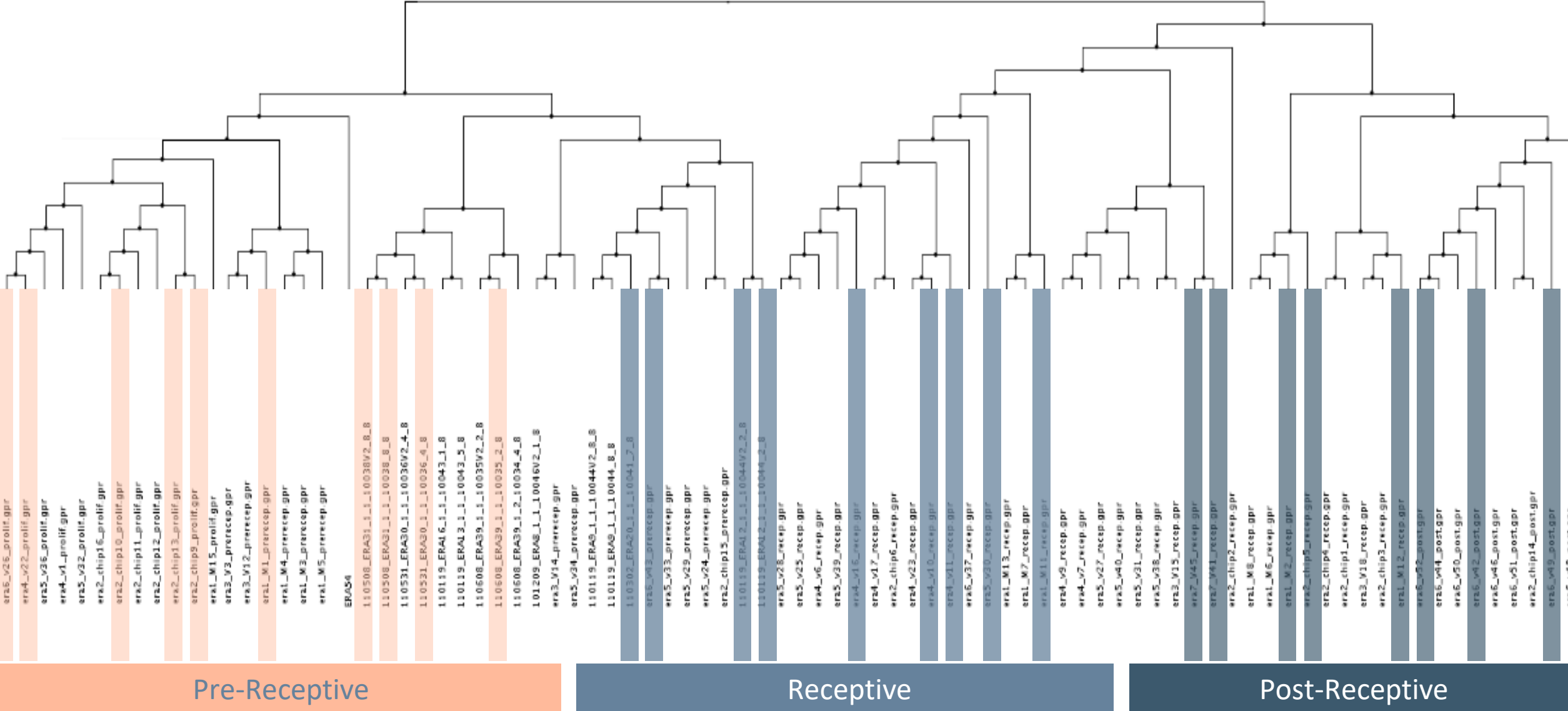
Talbi et al., 2005 (HG-U133 2.0) menstrual cycle



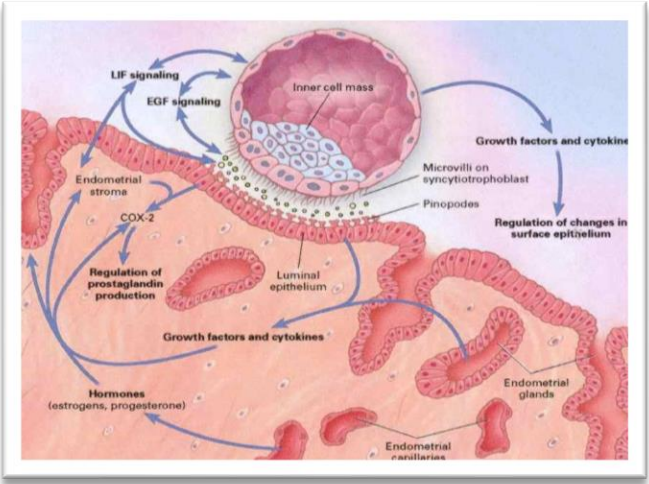
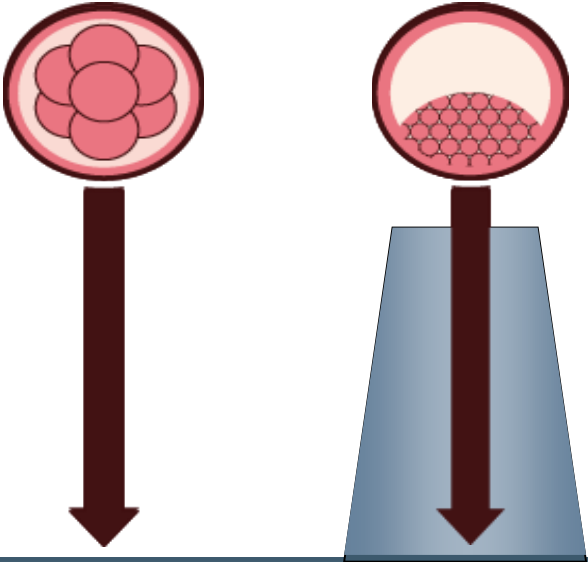
Endometrial Transcriptome Dynamics at the Single Cell Level



ERA classifies the molecular receptivity status of the endometrium

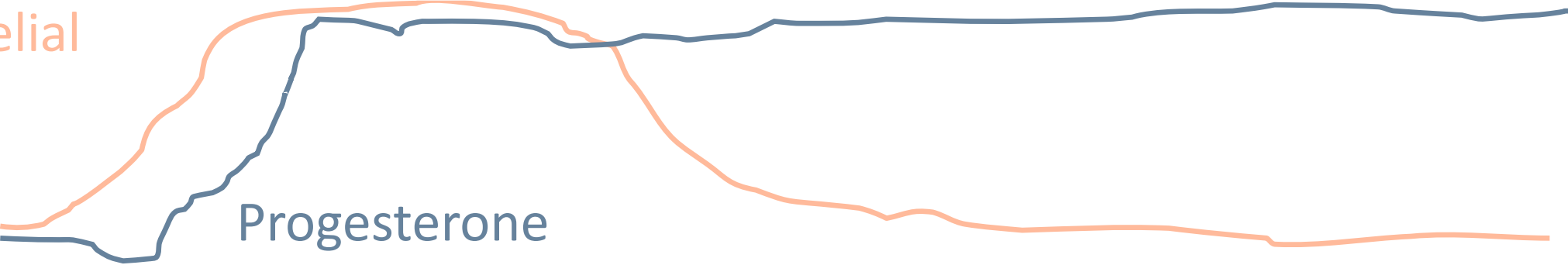


Window of Endometrial Receptivity

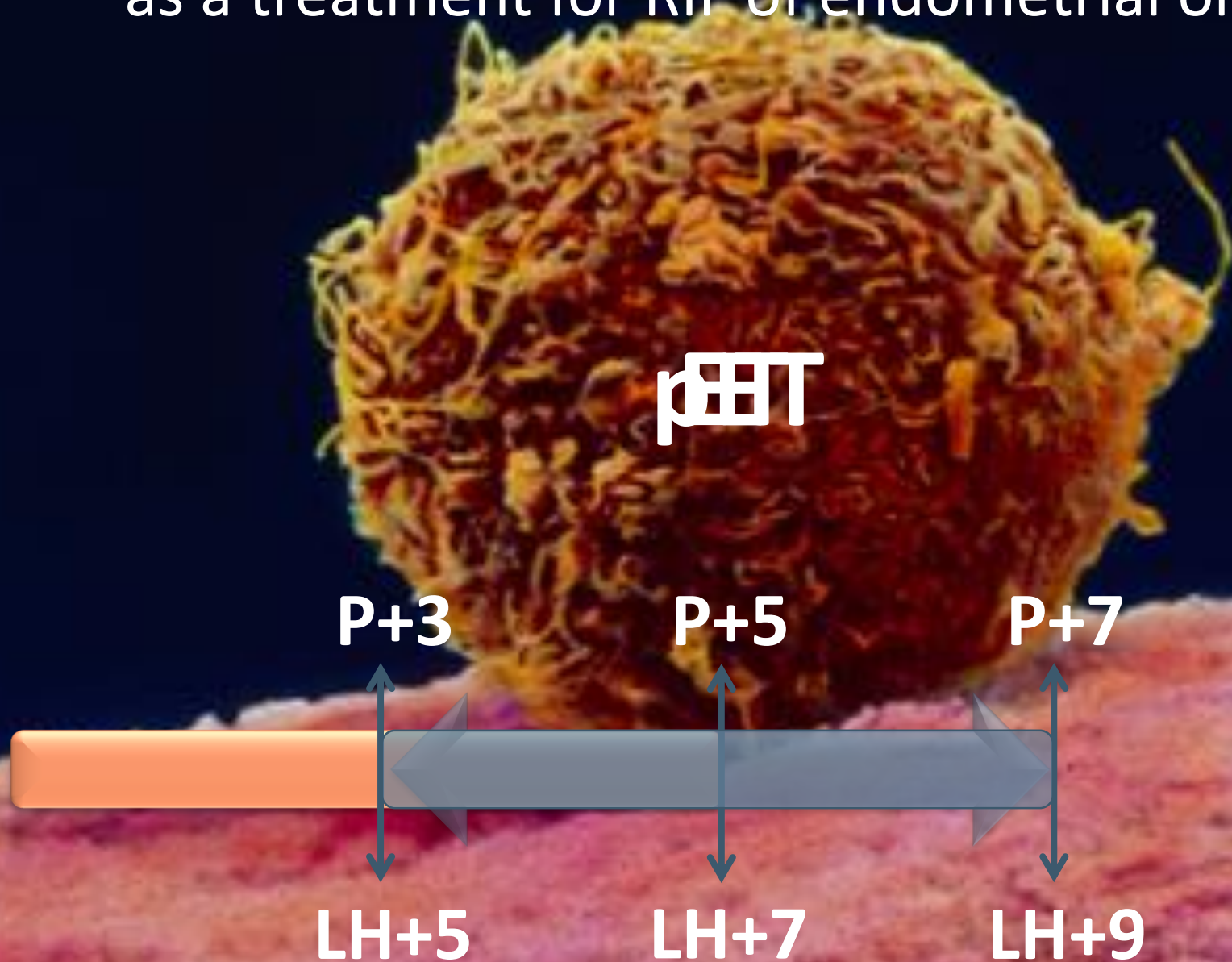


Epithelial
PR

Progesterone



Personalized embryo transfer (pET) as a treatment for RIF of endometrial origin



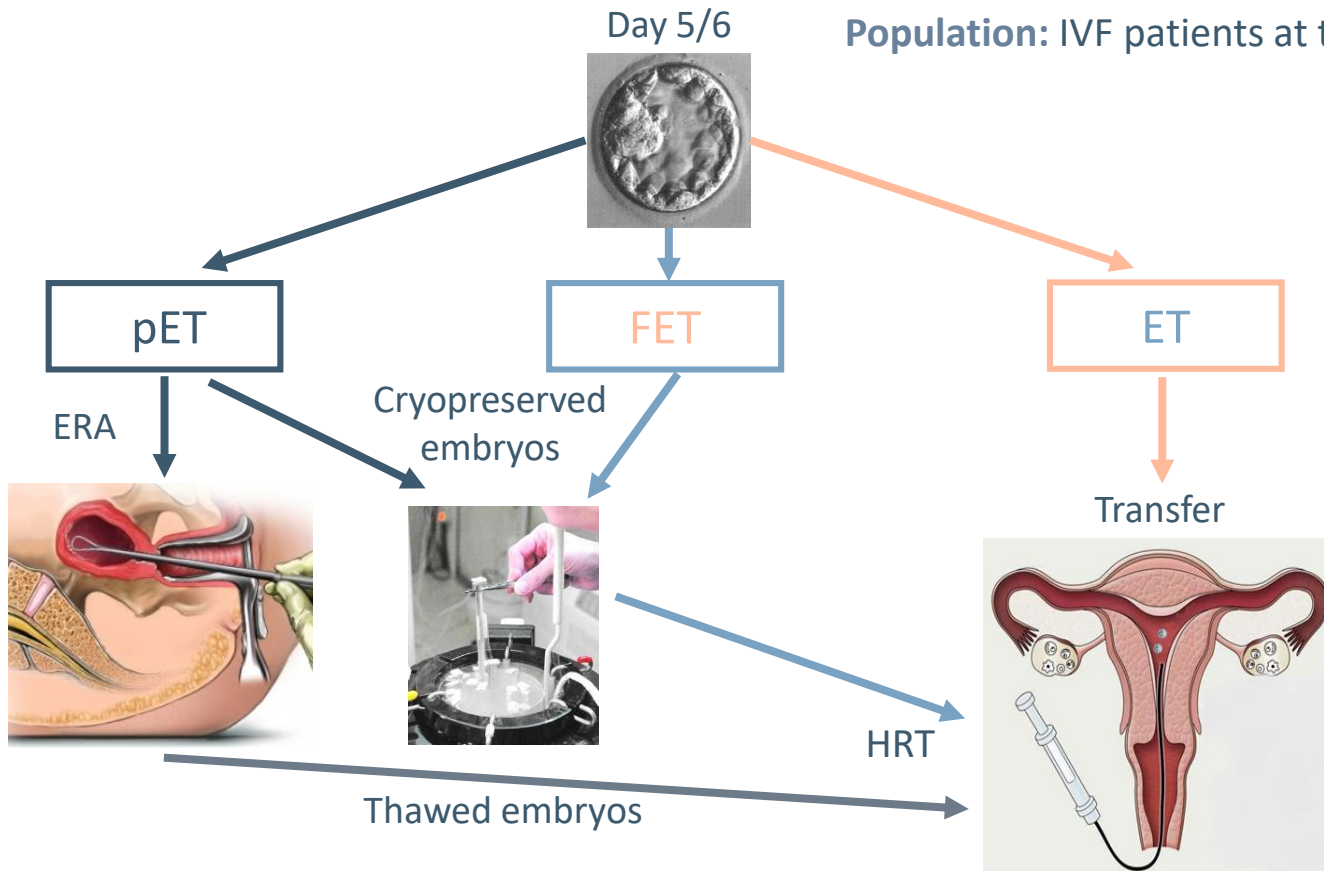
ERA Publications

YEAR	TITLE	JOURNAL
2015	Understanding and improving endometrial receptivity	Current Opinion in Obstetrics & Gynecology. 27(3):187-92
2015	Is endometrial receptivity transcriptomics affected in women with endometriosis? A pilot study	Reproductive BioMedicine Online. 31(5):647-54
2016	Diagnosis of endometrial-factor infertility: current approaches and new avenues for research	Geburtshilfe Frauenheilkd. 76(6): 699-703
2017	Does an increased body mass index affect endometrial gene expression patterns in infertile patients? A functional genomics analysis	Fertility and Sterility. 107(3):740-748.e2
2017	Endometrial function: facts, urban legends, and an eye to the future	Fertility and Sterility. 108(1):4-8
2017	Implantation failure of endometrial origin: it is not pathology, but our failure to synchronize the developing embryo with a receptive endometrium	Fertility and Sterility. 108(1):15-18
2017	Meta-signature of human endometrial receptivity: a meta-analysis and validation study of transcriptomic biomarkers	Scientific Reports. 7(1):10077
2017	Window of implantation transcriptomic stratification reveals different endometrial subsignatures associated with live birth and biochemical pregnancy	Fertility and Sterility. 108(4):703-710.e3
2018	Implantation failure of endometrial origin: what is new?	Curr Opin Obstet Gynecol. 30(4):229-236
2018	Inter-cycle consistency versus test compliance in endometrial receptivity analysis test	Journal of Assisted Reproduction and Genetics. 35(7):1307-1308

Evidence based medicine



ERA RCT – Study protocol overview



NIH U.S. National Library of Medicine
ClinicalTrials.gov

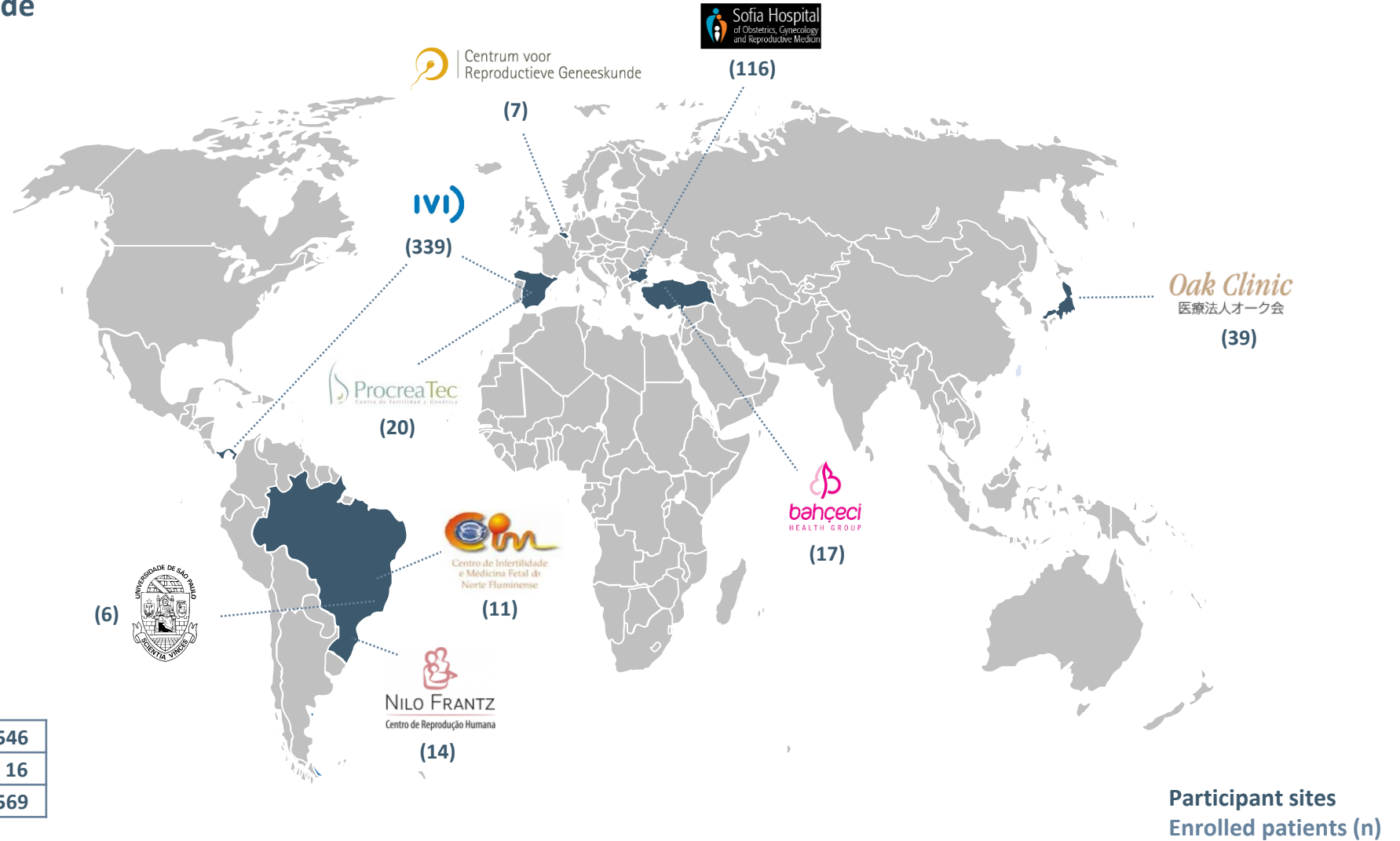
01954758
(1st Release: Sep 26th, 2013)
(Last update: Nov 4th, 2018)

First IRB/EC approval	July 2, 2013
EC FWA#	00027749
Last IRB/EC approval	April 28, 2016
FPFI	October 2013
Last LB (LPLV)	September 2018
Study length	5 years
Recruitment length	4 years

Primary objectives	Secondary objectives
LB and cumulative LB rates at 1-year follow-up (pET <i>versus</i> FET and pET <i>versus</i> ET)	Implantation and pregnancy rates, biochemical and clinical miscarriages, ectopic pregnancy, obstetrical, neonatal outcomes and cost-effectiveness.

ERA RCT Study Sites

16 Active sites worldwide



N EXPECTED	546
IRB/EC APPROVED SITES	16
N RECRUITED	569

ERA RCT Selection criteria

Inclusion Criteria

- > Patients undergoing IVF at the first appointment
- > Age \leq 37 years
- > BMI: 18.5 to 30
- > Normal ovarian reserve (AFC $>$ 8; FSH $<$ 8)
- > The stimulation protocol was decided by the doctor
- > Blastocyst transfer (day 5 or 6)

Exclusion Criteria

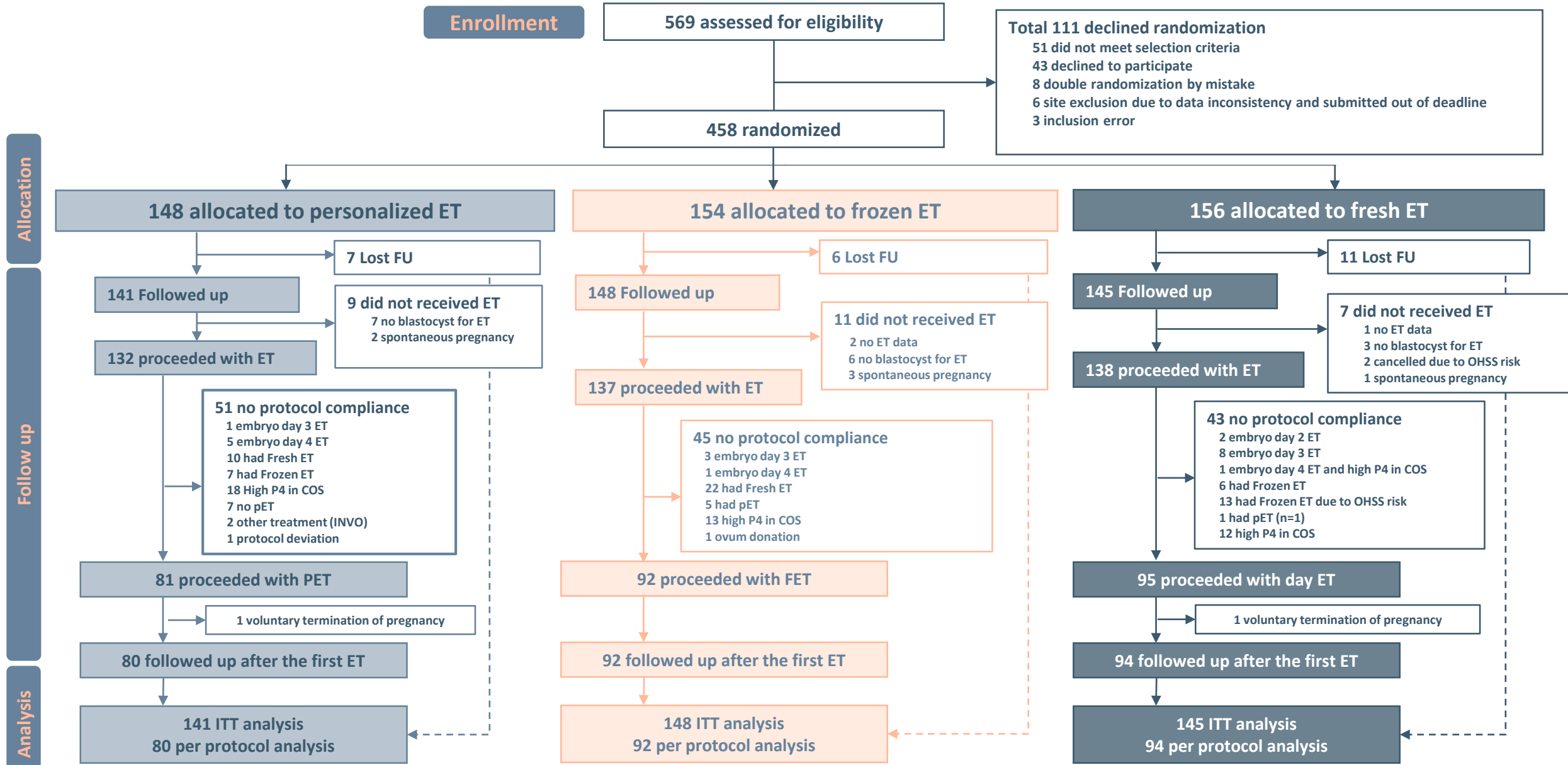
- > Recurrent miscarriage
- > Severe male factor ($<$ 2 million/ml)
- > Implantation failure ($>$ 3 failed cycles)
- > Any pathology affecting the endometrial cavity and hydrosalpinx must be previously operated.

Post-Randomization Exclusion Criteria

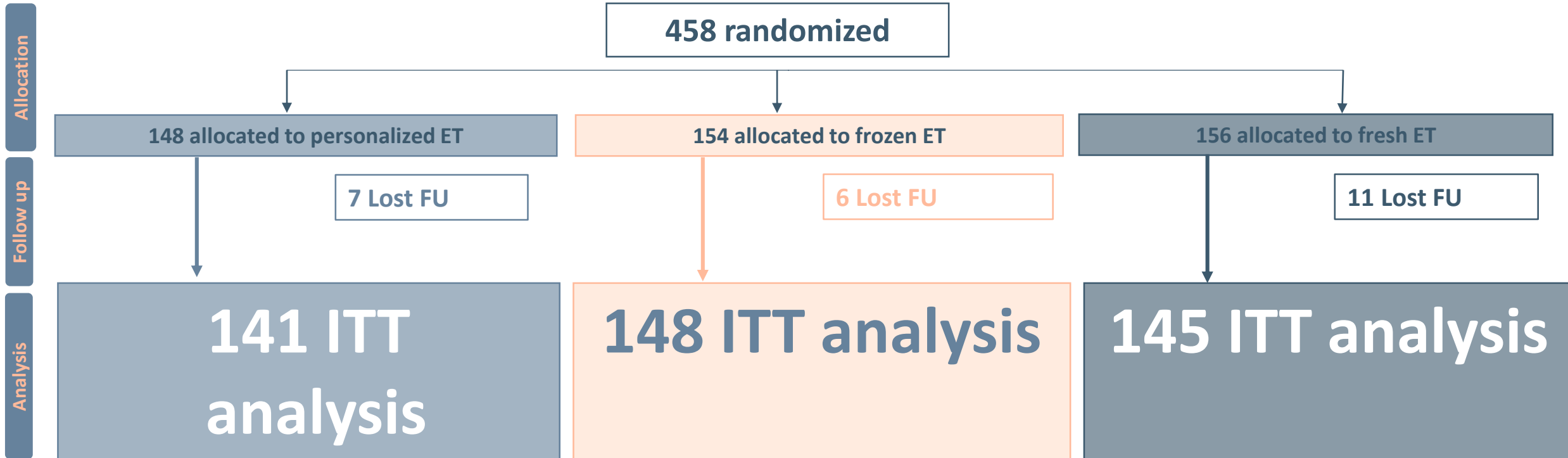
- > P4 level $>$ 1,5 ng/ml at the day of hCG administration in all groups
- > Absence of blastocysts for embryo transfer
- > Risk of OHSS in the fresh ET group

Note. PGT-A was NOT an inclusion criteria NEITHER an exclusion criteria

CONSORT Flow Diagram – ERA RCT



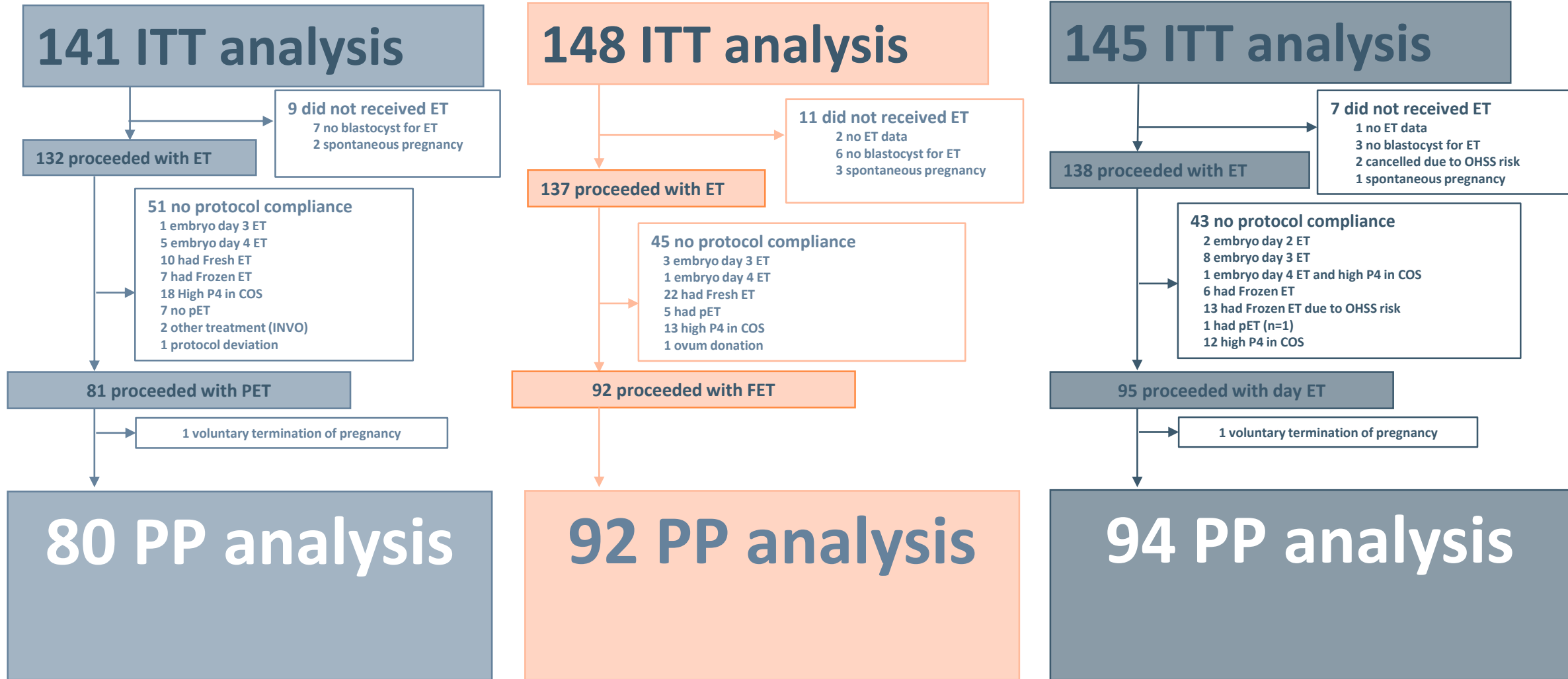
CONSORT Flow Diagram – ERA RCT



CONSORT Flow Diagram – ERA RCT

Follow up

Analysis



Demographic and clinical characteristics of the patients at baseline

	Personalized Embryo Transfer = 148)	pET (n	Frozen Embryo Transfer 154)	FET (n =	Fresh Embryo Transfer 156)	ET (n =
Age (y)	33 ± 3.1		32.8 ± 3.4		32.7 ± 3.3	
Body-mass index§	22.8 ± 2.9		22.9 ± 2.9		22.6 ± 2.8	
Ethnicity (%)						
Caucasian	122 (82.4)		127 (82.5)		129 (82.7)	
Asian	12 (8.1)		12 (7.8)		11 (7.1)	
Latin American	13 (8.8)		11 (7.1)		13 (8.3)	
African	0 (0.0)		4 (2.6)		1 (0.6)	
Other or unknow	1 (0.6)		0 (0.0)		2 (1.2)	
Current smoker	15 (10.1)		12 (7.8)		15 (9.6)	
Fertility history						
Duration of infertility (y)	3.1 ± 1.9		3.2 ± 2.1		2.9 ± 2.2	
No. of previous IVF failed						
0	109 (73.6)		104 (67.5)		112 (71.8)	
1	20 (13.5)		23 (14.9)		22 (14.1)	
2	10 (6.7)		10 (6.5)		12 (7.7)	
3	6 (4.0)		11 (7.1)		6 (3.8)	
Previous Deliveries						
1	11 (7.4)		16 (10.3)		17 (10.9)	
≥2	3 (2.0)		4 (2.6)		3 (1.9)	
Spontaneous clinical miscarriages						
1	23 (15.5)		26 (16.9)		24 (15.4)	
≥2	6 (4.0)		3 (1.9)		0 (0.0)	
Voluntary abortions	3 (2.0)		9 (5.8)		8 (5.1)	
Previous curettages (1 or 2)	12 (8.1)		11 (7.1)		10 (6.4)	
Ectopic pregnancies	8 (5.4)		3 (1.9)		4 (2.6)	
IVF indication (%)						
Male factor	65 (43.9)		78 (50.6)		50 (32.1)	
Tubal factor	20 (13.5)		31 (20.1)		33 (21.1)	
PCOS	27 (18.2)		20 (12.9)		14 (8.9)	
Ovarian disorders	4 (2.7)		5 (3.2)		7 (4.5)	
Endometriosis	21 (14.2)		9 (5.8)		13 (8.3)	
Unexplained	33 (22.3)		33 (21.4)		47 (30.1)	
Other or unknown‡	2 (1.3)		4 (2.6)		10 (6.4)	
Laboratory tests						
FSH (mU/mL)	5.9 ± 1.9a		6.6 ± 2.1		6.9 ± 2.0b	
AMH (ng/nL)	4.4 ± 3.6		3.7 ± 2.7		3.5 ± 2.9	

Cycle characteristics and embryological data.

ITT analysis

	Personalized Embryo Transfer pET (n = 141)	Frozen Embryo Transfer FET (n = 148)	Fresh Embryo Transfer ET (n = 145)
AFC	14.8 ± 6.3	14.9 ± 6.6	13.1 ± 5.9
Antagonist protocol	124 (87.9)	120 (81.1)	122 (84.1)
Agonist protocol	10 (7.1)	13 (8.8)	12 (8.3)
Total dose of FSH administered (IU)	1696.9 ± 687.8	1540.2 ± 635.2	1666.1 ± 669.8
Total dose of hMG administered (IU)	1167.03 ± 936	1202.3 ± 987	1165.1 ± 1042.5
P level at the day of ovulation induction	1.02 ± 0.7	0.93 ± 0.6	0.92 ± 0.8
Ovulation induction			
hCG	62 (44.0) ^a	57 (38.5) ^a	110 (75.9) ^b
Agonist	62 (44.0) ^a	67 (45.3) ^a	15 (10.3) ^b
Double triggering	7 (5.0)	7 (4.7)	7 (4.8)
Oocytes retrieved	12.4 ± 7.6	11.6 ± 6.0	10.5 ± 6.6
Fertilization technique			
ICSI	106 (75.2)	114 (77.0)	111 (76.6)
IVF	5 (3.5)	6 (4.1)	9 (6.2)
IVF/ICSI	21 (14.9)	13 (8.8)	21 (14.5)
Fertilization rate	1244/1633 (76.2)	1197/1531 (78.2)	1067/1379 (77.4)
Embryo Stage			
Cleavage stage	1/181 (0.6)	0 (0.0) ^a	7/211 (3.3) ^b
Morula	2/181 (1.1)	1/208 (0.5)	1/211 (0.5)
Early Blastocyst	12/181 (6.6)	11/208 (5.3)	5/211 (2.4)
Cavitated blastocyst	40/181 (22.1)	47/208 (22.6)	48/211 (22.7)
Expanded Blastocyst	93/181 (51.4)	100/208 (48.1)	109/211 (51.7)
Hatching Blastocyst	33/181 (18.2)	49/208 (23.6)	41/211 (19.4)
Blastocyst development rate	648/1248 (51.9)	636/1239 (51.3)	561/1093 (51.3)
Day of embryo development at transfer			
2	0 (0.0)	0 (0.0)	2 (1.4)
3	10 (7.1)	4 (2.7)	10 (6.9)
4	7 (5.0) ^a	4 (2.7)	0 (0.0) ^b
5	98 (69.5) ^a	112 (75.7)	119 (82.1) ^b
6	16 (11.3)	17 (11.5) ^a	6 (4.1) ^b
Embryo Quality			
ICM			
"A" grade	48/149 (32.2)	70/183 (38.3)	56/183 (30.6)
"B" grade	84/149 (56.4)	92/183 (50.3)	110/183 (60.1)
"C" grade	17/149 (11.4)	21/183 (11.5)	17/183 (9.3)
TE			
"A" grade	36/149 (24.2)	56/183 (30.6)	46/183 (25.1)
"B" grade	85/149 (57)	95/183 (51.9)	96/183 (52.5)
"C" grade	28/149 (18.8)	32/183 (17.5)	40/183 (21.9)
PGT-A cases	6 (4.3)	4 (2.7)	3 (2.1)
Number of transferred embryos	1.52 ± 0.5	1.61 ± 0.5	1.63 ± 0.5
Thawed HRT embryo transfer data			
No. of days of E2	15.5 ± 3.8 ^a	16.6 ± 3.8 ^b	NA
Endogenous P levels	0.2 (0.03-1.4)	0.29 (0.05-11.03)	NA
Hours exogenous P admin.	120 ± 14.4	117.8 ± 9.7	NA
Hours exogenous P admin. (range)	65.2-163.4 (98.2)	66.4-151.2 (84.8)	NA
Time between COS and embryo transfer (months)	3.2 ± 2.4 ^a	2.1 ± 1.4 ^b	NA

Reproductive outcomes at the first embryo transfer and cumulative during 1-year follow-up*. ITT analysis

	pET (n = 141)	FET (n = 148)	ET (n = 145)	pET vs FET		pET vs ET	
				Relative risk (95% CI)	P-value	Relative risk (95% CI)	P-value
No. of transfers	132	137	138				
Pregnancy rate	83 (58.9)	73 (49.3)	84 (57.9)	1.22 (0.96-1.56)	0.12	1.02 (0.80-1.29)	0.9
Implantation rate	88/201 (43.8)	80/220 (36.4)	97/225 (43.1)	1.17 (0.96-1.43)	0.14	1.01 (0.83-1.24)	0.92
LB rate	57 (40.4)	51 (34.5)	64 (44.1)	1.14 (0.90-1.44)	0.33	0.92 (0.73-1.18)	0.55
Singleton	49/57 (86)	40/51 (78.4)	45/64 (70.3)	1.31 (0.75-2.29)	0.32	1.76 (0.95-3.25)	0.049

Cumulative Pregnancy Rate

pET (n = 141)	FET (n = 148)	ET (n = 145)	pET vs FET		pET vs ET	
			Relative risk (95% CI)	P-value	Relative risk (95% CI)	P-value
132/141 (93.6%) ^a	118/148 (79.7%) ^b	117/145 (80.7%) ^b	2.29 (1.27-4.11)	0.0005	2.18 (1.22-3.89)	0.0013

Cumulative pregnancy rate	132/141 (93.6) ^a	118/148 (79.7) ^b	117/145 (80.7) ^b	2.29 (1.27-4.11)	0.0005	2.18 (1.22-3.89)	0.0013
Cumulative LB rate	88/141 (62.4)	82/148 (55.4)	85/145 (58.6)	1.16 (0.91-1.49)	0.23	1.08 (0.85-1.39)	0.55
Singleton	75/88 (85.2)	67/82 (81.7)	58/85 (68.2)	1.14 (0.74-1.74)	0.54	1.73 (1.08-2.78)	0.011
Multiple (all twins)	13/88 (14.8)	15/82 (18.3)	27/85 (31.8)	0.88 (0.57-1.35)	0.54	0.58 (0.36-0.92)	0.011
Cumulative clinical miscarriages	24/132 (18.2)	17/118 (14.4)	5/117 (4.3)	1.13 (0.85-1.51)	0.49	1.69 (1.36-2.09)	0.0006
Cumulative biochemical pregnancies	19/132 (14.4)	16/118 (13.6)	23/117 (19.7)	1.03 (0.74-1.44)	1	0.83 (0.58-1.18)	0.31
Cumulative ectopic pregnancies	1/132 (0.8)	1/118 (0.8)	1/117 (0.9)	0.95 (0.24-3.81)	1	0.94 (0.23-3.79)	1
Transfers per patient	2.63 ± 1.14	2.28 ± 0.70	2.62 ± 0.73	0.35 (-0.4-0.4)	0.1	0.01 (-0.43-0.45)	1

Reproductive outcomes at the first embryo transfer and cumulative during 1-year follow-up*. Per protocol analysis

		pET (n = 80)	FET (n = 92)	ET (n = 94)	pET vs FET		pET vs ET	
					Relative risk (95% CI)	P-value	Relative risk (95% CI)	P-value
Pregnancy rate		58 (72.5)	50 (54.3)	55 (58.5)	1.56 (1.07-2.29)	0.01	1.42 (0.98-2.08)	0.057
Implantation rate	pET (n = 80)	FET (n = 92)	ET (n = 94)	pET vs FET		pET vs ET		
LB rate				Relative risk (95% CI)	P-value	Relative risk (95% CI)	P-value	
Singleton								
Multiple (all twins)								
C Pregnancy rate								
B Pregnancy rate	58 (72.5%)	50 (54.3%)	55 (58.5%)	1.56 (1.07-2.29)	0.01	1.42 (0.98-2.08)	0.057	
E Implantation rate	63/110 (57.3%)	60/139 (43.2%)	58/150 (38.6%)	1.37 (1.03-1.82)	0.03	1.54 (1.15-2.05)	0.004	
N Implantation rate								
T LB rate	45 (56.2%)	39 (42.4%)	43 (45.7%)	1.35 (0.97-1.86)	0.09	1.26 (0.91-1.74)	0.17	
C LB rate								
C Cumulative pregnancy rate	76/80 (95%)	65/92 (70.6%)	59/94 (62.8%)	4.18 (1.65-10.56)	0.0001	5.49 (2.14-14.06)	0.0001	
C Cumulative pregnancy rate								
C Cumulative LB rate	57 (71.2%)	51 (55.4%)	46 (48.9%)	1.47 (1.01-2.13)	0.04	1.71 (1.17-2.49)	0.003	
C Cumulative LB rate								
C Cumulative ectopic pregnancies	0 (0.0)	0 (0.0)	1/59 (1.7)					
C Transfers per patient	3.05 ± 1.61	2.13 ± 0.34	3.5 ± 1.29	0.92 (-0.11-1.97)	0.09	-0.45 (-2.13-1.24)	1	

Obstetrical, delivery and neonatal outcomes. Per protocol analysis

	Personalized-Embryo Transfer. pET (n = 80)		Frozen-Embryo Transfer. FET (n = 92)		Fresh-Embryo Transfer. ET (n = 94)	
	No. of outcomes		No. of outcomes		No. of outcomes	
Ovarian hyperstimulation	80	0 (0.0)	92	0 (0.0)	94	1 (1.1)
Obstetrical outcomes	45		39		43	
Gestational diabetes		2 (4.4)		1 (2.6)		1 (2.3)
HBP		1 (2.2)		0 (0.0)		0 (0.0)
Placenta previa		1 (2.2)		1 (2.6)		0 (0.0)
Retrocorial hematoma		0 (0.0)		1 (2.6)		1 (2.3)
Abruption		1 (2.2)		0 (0.0)		0 (0.0)
Vasa previa		1 (2.2)		0 (0.0)		0 (0.0)
Still birth		1 (2.2)		1 (2.6)		0 (0.0)
Type of delivery	40		35		43	
C-Section		10 (25.0)		14 (40.0)		15 (34.9)
Vaginal		30 (75.0)		21 (60.0)		28 (65.1)
Neonatal outcomes‡	40		35		43	
Neonatal mortality		0 (0.0)		1 (2.9)		0 (0.0)
Gestational age (weeks)	38	38.03 ± 3.1	34	38.03 ± 2.9	42	38.33 ± 1.6
Preterm birth <37 weeks	38	5 (13.2)	34	6 (17.6)	42	4 (9.5)
Birth weight (g)	23	3170.6 ± 646.9	30	2868.5 ± 629.1	34	2912.6 ± 573.6
Birth weight in singletons	17	3484.4 ± 321.6	14	3362.5 ± 402	22	3210.68 ± 375.6
Birth weight in twins	6	2281.7 ± 476.7	16	2436.2 ± 444.9	12	2366.2 ± 463.2
Birth weight <2500 g	23	4 (17.4)	30	10 (33.3)	34	6 (17.6)
Birth height (cm)	17	49.9 ± 2.7	27	48.3 ± 2.6	30	48.9 ± 2.3
APGAR score						
1 minute	28	8.7 ± 1.5	21	9 ± 0.8	18	9.22 ± 0.7
5 minutes	24	9.5 ± 0.9	16	9.9 ± 0.2	12	9.7 ± 0.4
Congenital anomalies		0 (0.0)		0 (0.0)		0 (0.0)

Cost-effectiveness estimation per baby at home at the first attempt

	Personalized-Embryo Transfer pET (n = 80)		Frozen-Embryo Transfer FET (n = 92)		Fresh-Embryo Transfer ET (n = 94)	
No. of deliveries with at least 1 LB at the first attempt	45		39		43	
	EU	USA	EU	USA	EU	USA
IVF lab cost	€ 5.190	\$ 11.825	€ 5.190	\$ 11.825	€ 5.590	\$ 12.325
Drug cost	Personalized-Embryo Transfer pET (n = 80)		Frozen-Embryo Transfer FET (n = 92)		Fresh-Embryo Transfer ET (n = 80)	
Vitrification cost						
	EU	USA	EU	USA	EU	USA
Estimated cost of a delivery with at least 1 LB at the first attempt	€ 19.555	\$ 42.658	€ 23.448	\$ 50.482	€ 15.674	\$ 36.780
Estimated cost of a delivery with at least 1 LB at the first attempt	€ 19.555	\$ 42.658	€ 23.448	\$ 50.482	€ 15.674	\$ 36.780

ERA RCT Take-home messages





> By ITT analysis:

- **Cumulative PR** was significantly  in the pET group (**93.6%**) vs FET (**79.7%**) and ET (**80.7%**).

> By PP analysis,

- **LB**  **14 pp** and **11 pp** versus FET and ET that was non statistically significant.

Statistically significant improvement in:

- **Cumulative LBR**  **16 pp** and **22.1 pp** versus FET and ET.
- **PR**  **18.2 pp** and **14 pp** versus FET and ET.
- **IR**  **14 pp** and **18.4 pp** versus FET and ET.
- **Cumulative PR**  **21.4 pp** and **32.1 pp** versus FET and ET.

> Similar clinical outcome between FET and ET.

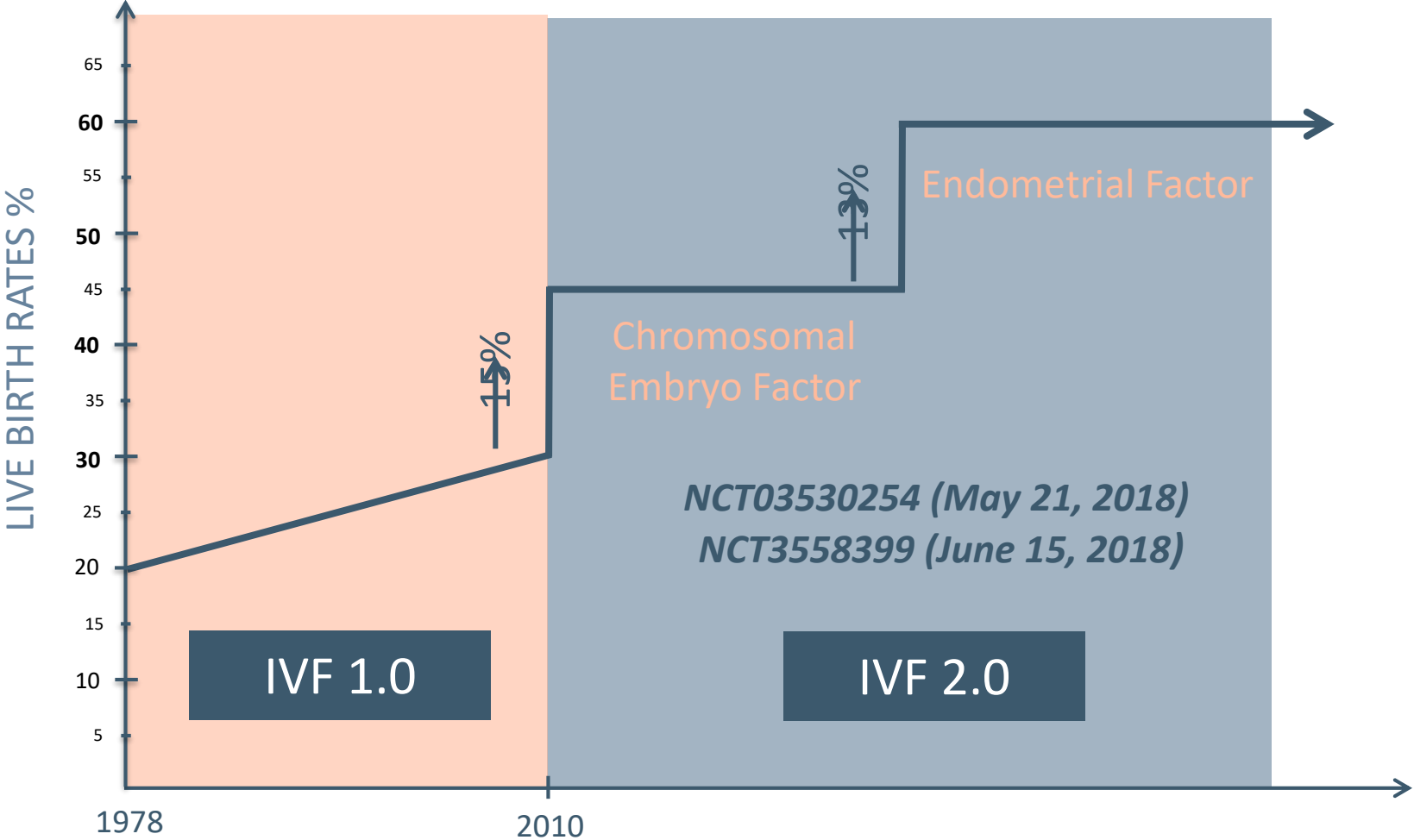
> Obstetrical, delivery and neonatal outcomes were not different.

Limitations, reasons for caution

- ✓ The main limitation of our study is the unexpected added 20% patient drop-out rate versus 30% initially planned (16 study sites in 3 different continents).
- ✓ The study was powered to detect statistical differences for a 15-percentage points increase in the primary outcomes in the pET group versus FET or ET.
- ✓ This is the first RCT to provide proof-of-principle evidence for the potential of using a personalized diagnosis of the endometrial factor in the work-up of the infertile couple at the **first** appointment.



Wider implications



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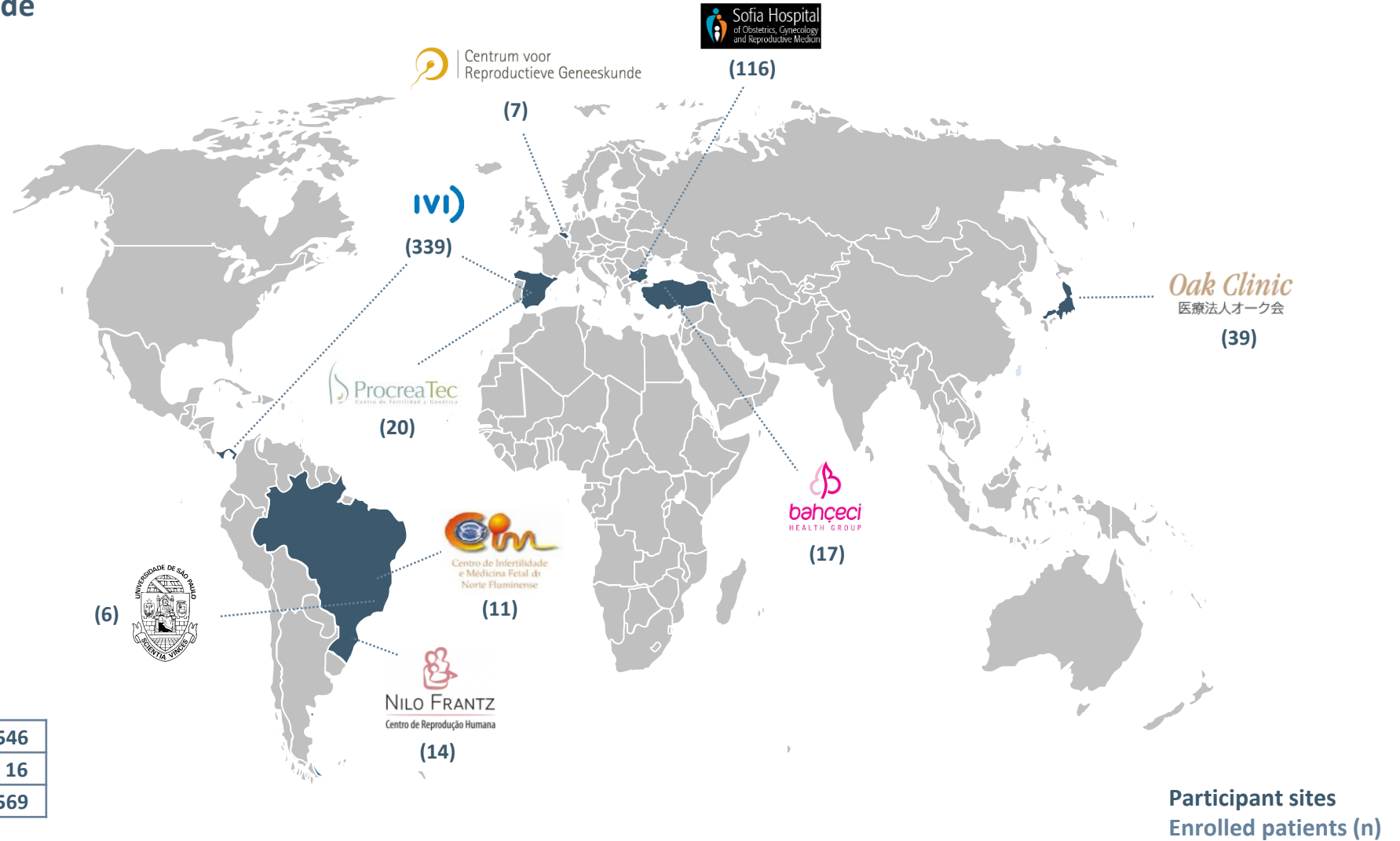
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ERA RCT Study Sites

16 Active sites worldwide



N EXPECTED	546
IRB/EC APPROVED SITES	16
N RECRUITED	569

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