



**Barcelona Tissue Bank**  
BANC DE SANG I TEIXITS



# WP 8 – ART GTP tool

ART dream team  
1<sup>st</sup> Technical meeting ART  
Ghent  
03/03/2017



Ministarstvo  
zdravlja  
Za zdravlje. Zajedno.



Krajowe Centrum  
Bankowania Tkanek i Komórek



Universitair Ziekenhuis Gent



Kliniek **SINT-JAN**  
Clinique **SAINT-JEAN**



# WP Presentation

- Description (Goals and Expected Results)
- Involved Partners and Collaborating Experts
- Timelines and Milestones
- Outcomes (Deliverables)
- Work Plans (When, what and how)

# Description

- Determine criteria and parameters essential for implementation of ART products / clin. appl.
- Identification of ART products and clin. appl. and their status of validation
- Expected result = tool (web based or APP based) to distinguish and classify treatment and procedures through lab KPI and health follow up

# What is there already

- Followup patients ART treatments ~ national registries (European IVF monitoring (EIM ESHRE) through national representatives (39 countries))
- Guideline committee (ESTEEM trial)
- Self criticism in ART:

Reproductive BioMedicine Online (2013) 27, 742–746



ELSEVIER

www.sciencedirect.com  
www.rbmonline.com

SYMPOSIUM: FUTURES IN REPRODUCTION  
REVIEW

**The wobbly evidence base of reproductive medicine**



JLH Evers

Maastricht University Medical Centre, Maastricht, The Netherlands  
E-mail address: j.l.h.evers@maastrichtuniversity.nl

**Human Reproduction, Vol.29, No.3 pp. 413–417, 2014**

Advanced Access publication on January 15, 2014 doi:10.1093/humrep/det463

human  
reproduction

**ORIGINAL ARTICLE ESHRE pages**

**Beyond the dichotomy: a tool for distinguishing between experimental, innovative and established treatment<sup>†</sup>**

Veerle Provoost<sup>1,\*</sup>, Kelly Tilleman<sup>2</sup>, Arianna D'Angelo<sup>2</sup>,  
Petra De Sutter<sup>2</sup>, Guido de Wert<sup>1</sup>, Willianne Nelen<sup>2</sup>,  
Guido Pennings<sup>1</sup>, Francoise Shenfield<sup>1</sup>, and Wybo Dondorp<sup>1</sup>



ELSEVIER

www.sciencedirect.com  
www.rbmonline.com

SYMPOSIUM: FUTURES IN REPRODUCTION  
REVIEW

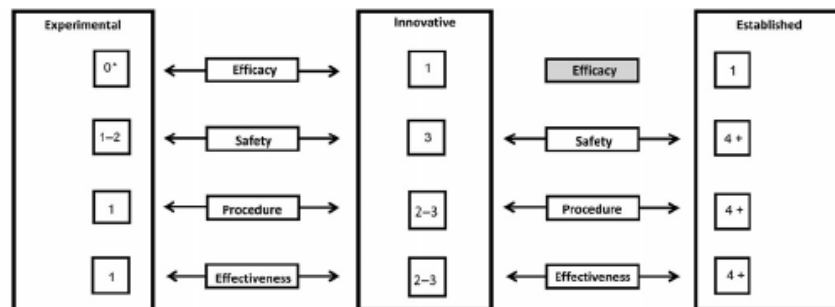
**How should we assess the safety of IVF technologies?**

Daniel R Brison<sup>a,b,\*</sup>, Stephen A Roberts<sup>c</sup>, Susan J Kimber<sup>d</sup>



bestanden te converte  
naar PDF.

ient



**Figure 1** Sequential four-criterion assessment tool to consider the transition of a treatment from experimental through innovative to established.  
\*Numbers represent the scores at either end of the threshold for each of the four criteria for the first transition (from experimental to innovative) and for each of the three last criteria for the second transition (from innovative to established).

**Table 1** Scoring key used in the tool for distinguishing between treatments.

Criterion	Definition	Scoring
Efficacy	Proof of principle	0: No proof of principle has been demonstrated 1*: Proof of principle has been demonstrated
Safety	The safety of the procedure, referring to the patient as well as the future children	1: Considered safe in animals 2: Reassuring preclinical data 3*: Reassuring short-term data in human (up to at least 3 months post-delivery) in peer-reviewed journals 4**: Reassuring mid-term data in human (up to at least 5 years post-delivery and including data on psychological development) in peer-reviewed journals 5: Reassuring long-term data in human (up to at least 25 years post-delivery, including data on psychological development and preferably on fertility) in peer-reviewed journals
Procedure	Procedural reliability and transparency: the similarity or variability of the procedure in different laboratories and the potential for implementation by other centres	1: No procedure has been described yet, or the procedure varies enormously between laboratories 2*: Technical performance of the procedure is highly variable between laboratories 3: Technical performance of the procedure is relatively comparable between laboratories 4**: Technical performance of the procedure is highly comparable between laboratories 5: Throughout different centres, the procedure is considered a routine technique with common technical performance
Effectiveness	The likelihood of producing the desired outcome compared with outcome of conventional, established ART techniques	1: Completely unknown, doubtful or extremely low 2*: Low 3: Reasonable 4: Acceptable but not as high as established ART treatment 5**: As high or higher than established ART techniques

An example of an established treatment is IVF.

ART, assisted reproduction techniques.

\*Threshold for innovative treatment.

\*\*Threshold to move from innovative to established treatment for the criteria 'safety', 'procedure' and 'effectiveness'. 'Efficacy' is an all-or-nothing criterion that only has one threshold (1, to move from experimental to innovative treatment).



# Partners and Collaborating Experts

- EIM link and SQUART: Iona Rugescu (RO) biol
- SQUART: Zdravka Veleva (FIN) MD
- Experts: Francesco Lombardo (I)(MD), Gueorgui Nikolov (BU) (MD)
- Lab KPI people: Martine Nijs (B – NL 😊) (Embryolab academy) – Annelies Tolpe (B)
- ESHRE Guideline committee: Nathalie Vermeulen (B)  
Ethics and law: Veerle Provoost (B)

# Timelines and Milestones

- Get partners on board
- Put ART flavor in generic tool
- Define criteria (KPI laboratories: embryo development, short term vs long term followup)
- Define balance in follow up (criteria vs validation labo process vs clin appl)
- Look for consensus in ART (national representatives and experts)
- Test criteria (for established procedures (ICSI, IVF) and for innovative procedures (vitrification of oocytes) and experimental (?): IVM (aspirated vs ivimova)
- Established techniques from consensus in compendium
- Promote GTP management tool

# Timelines and Milestones

- Get partners on board \_\_\_\_\_ JULY16
- Put ART flavor on tool \_\_\_\_\_ FEBR17 \_\_ MAY17
- Define ART criteria and balance \_\_\_\_\_ JULY17
- Consensus in ART \_\_\_\_\_ OCT17\_ FEBR18
- Test criteria (FoR) \_\_\_\_\_ OCT17\_ FEBR18
- Fill compendium with established ART techniques \_MR 18 – JULY 18
- Finalize GTP in ART \_\_\_\_\_ FEBR18
- Promote GTP management tool \_\_\_\_\_ JULY18





**Barcelona Tissue Bank**  
BANC DE SANG I TEIXITS



# Outcome

## GTP TOOL *our ABC*

ART consensus based

Balanced lab KPIs vs follow-up children

Classification based on consensus criteria



# Work Plans

- **Strategies:**  
use ESHRE as fundament (SQUART, EIM, guideline committee)  
what is good = keep (e.g. national registries, EIM)  
Share = Show that we are in fact TE ;-)
- **Meetings:** ESHRE meetings as meeting point– 1 extra meeting  
Brussels – multimedia
- **Structure and contents:** keep close contact with other TC  
partners both in structure and content = monitor



**Barcelona Tissue Bank**  
BANC DE SANG I TEIXITS



# Thank you!



Krajowe Centrum  
Bankowania Tkanek i Komórek



Universitair Ziekenhuis Gent



Kliniek **SINT-JAN**  
Clinique **SAINT-JEAN**

