### FGAI4H-L-034-A01

E-meeting, 19-21 May 2021

|  | Source:   | Merck KGaA (Darmstadt, Germany)   |  |  |  |
|--|-----------|---|--|--|--|
|  | Title:    | Proposal for new topic group: AI for Human<br>Reproduction and Fertility – Att.1: Presentation  |  |  |  |
|  | Purpose:  | Discussion  |  |  |  |
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|  | Abstract: | This PPT summarizes the content of L-034 with a proposal for a<br>new topic group on AI for fertility for presentation and<br>discussion during the meeting. The topic group on AI for fertility<br>will address challenges and considerations that should be<br>assessed when developing AI solutions for clinical applications. |  |  |  |

## Infertility is a disease that impacts one in six couples and its treatment is unique, complex and divided in different phases



### AI publications in medicine are growing very fast since a few years – Fertility is catching up as well





## Advanced analytics and AI enables the creation of new products and services that improve treatment outcomes and efficiency

| Patient Identification  | Consultation  | Stimulation & Triggering   | ART Lab   | Transfer & Pregnancy  |
|---|---|--|---|---|
| Broader patient<br>identification due to<br><b>identification of</b><br><b>new infertility</b><br><b>indicators</b> and<br>correlations of<br><b>behavioral patterns</b><br>through big data<br>analytics | Improved patient<br>expectations<br>management<br>through predictive<br>analysis and<br>individual prediction<br>of IVF success | Higher treatment<br>success rates through<br><b>personalized</b><br><b>treatment protocol</b><br>individualized<br>interventions if<br>necessary | Support clinical<br>decision making<br>throughout all lab<br>process steps based<br>on advanced AI<br>algorithms and<br>computer vision to<br>identify most viable<br>embryos | Increasing successful<br>transfers and<br><b>improving</b><br><b>receptivity</b> through<br>intelligent algorithms<br>and biomarkers that<br><b>help to determine</b><br><b>the status of the</b><br><b>endometrium</b> |
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Data-driven business opportunities delivered through AI, data analytics, and connectivity solutions add value throughout the entire IVF journey

# Advanced analytics and AI enables the creation of new products and services that improve treatment outcomes and efficiency





Most AI solutions are currently performed without any standardized process, regulatory or harmonized quality standards

## Given the maturity and the recent developments of AI in Fertility, there are several challenges that need to be addressed to ensure safety, reliability and transparency

### Challenges –

#### Data

- Heterogeneity of data sources
- Data quality and data size
- Bias in the data, noise or partial evidence

#### Validation

- Proper validation on hold-out data and lack of benchmark
- Lack of clinical prospective validation

### - Proposal -

#### Data

- Definition of quality standard and guidelines to harmonize data
- Facilitate integration and collection of data from different sources

#### Validation

- Definition of guidelines for proper development and validation
- Creation of benchmarks



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