

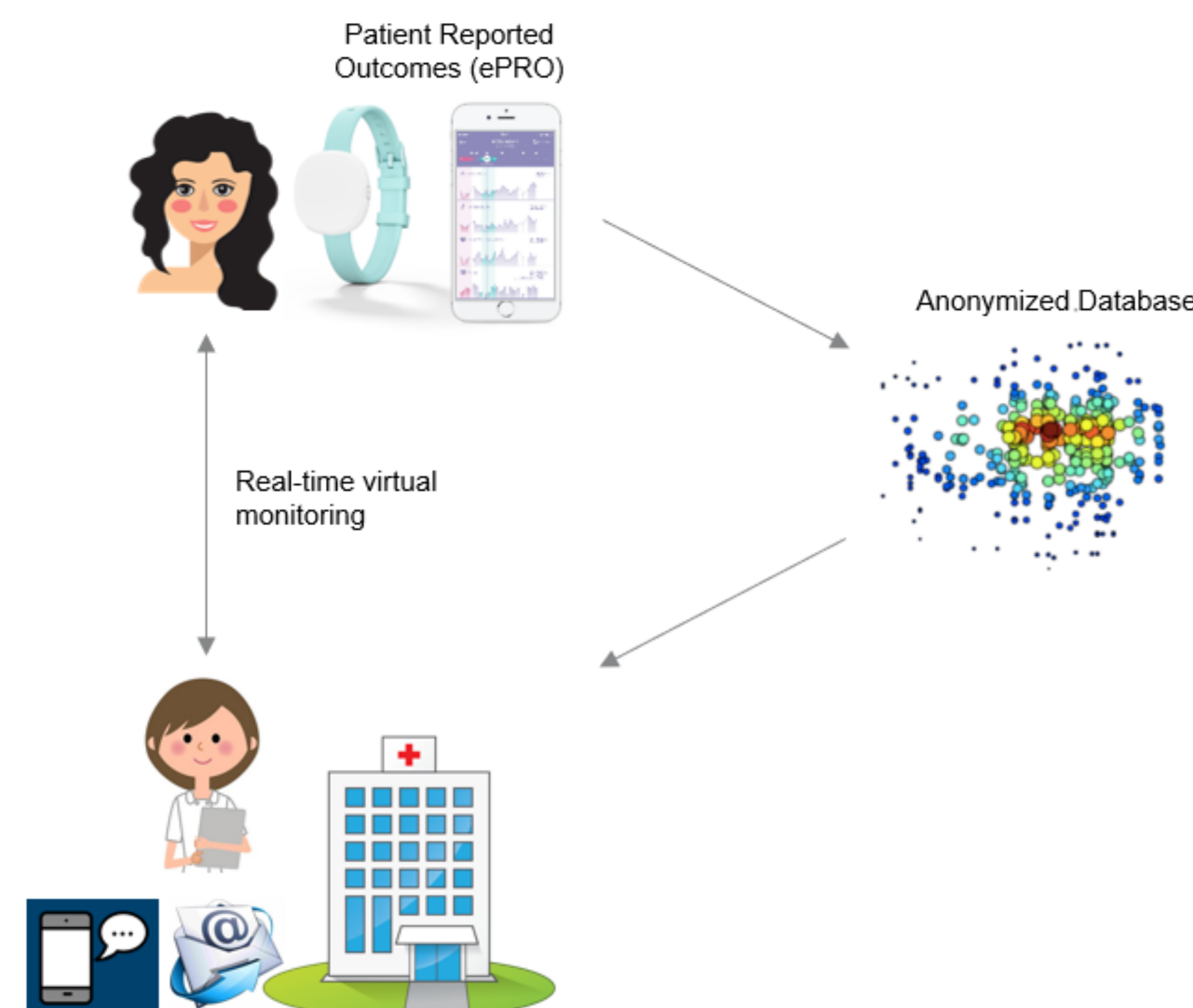


PURPOSE / OBJECTIVES

- Loss to follow-up and missing data are two of the most common reasons for clinical studies failure
- Implementing digital methods in clinical trials has the potential to increase participant retention and procedural compliance, while reducing participant burden and maintaining their satisfaction
- We conducted an innovative trial utilizing only digital methods to assess the accuracy of a wearable medical device for fertility tracking, and therein we examined participants' retention, compliance, and satisfaction

MATERIAL & METHODS

- Prospective longitudinal study in women to assess the relative accuracy of a multi-parameter wearable fertility device to detect ovulation ("Ava Fertility Tracker", Ava AG)
- Recruitment remotely through social media, online registration platforms, and email invitations as well as through one face to face enrollment visit
- Participants (n=66) wore the device nightly for up to 6 cycles, syncing their bracelet, taking body temperature measurements, and urinary luteinizing hormone tests to determine their ovulation day each cycle
- All patient-reported outcomes and data were collected from the wearable via a mobile app, wherein the study coordinator could monitor daily participant activity and send procedures reminders when forgotten
- Participants could contact the study coordinator for study-related requests and an independent customer support team for technical support
- Lastly, we surveyed the participants' perception of the site-less study design



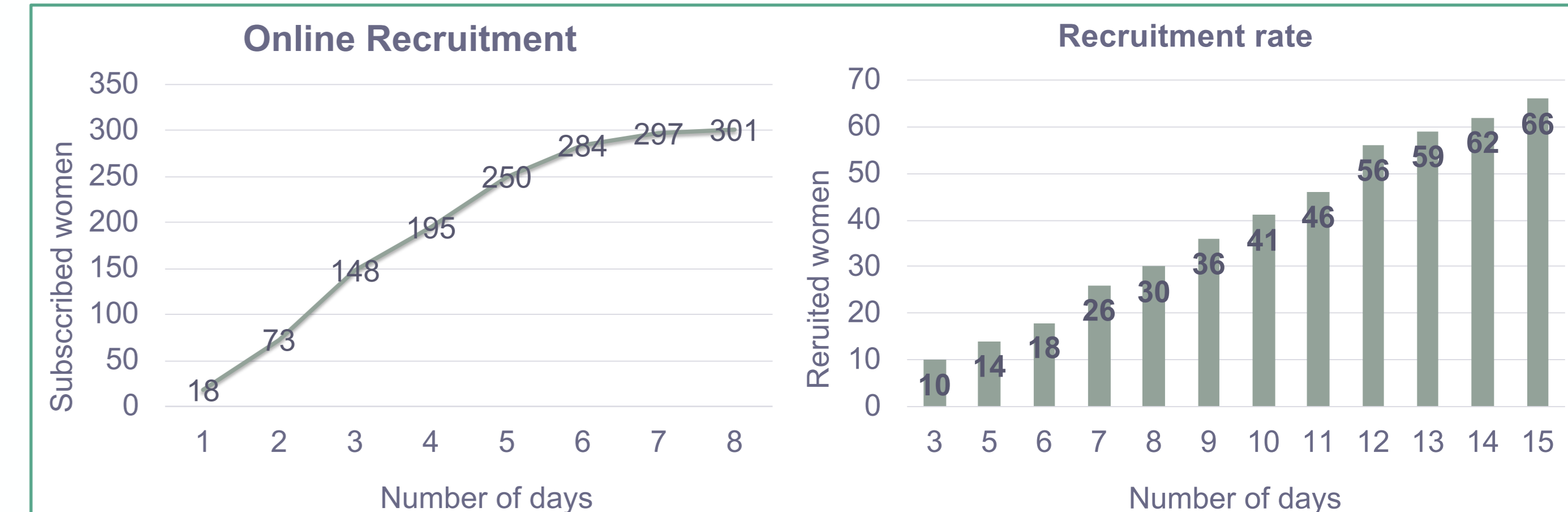
Based on our findings, digital health technologies:

- Lead to faster recruitment (n=66 in 15 days)
- Result in high patient satisfaction (98% reported)
 - Improve participant retention (92% study completion)
 - Decrease data loss through real-time virtual participant monitoring (87% compliance)
 - Are easy to integrate into daily life (61% reported)
- Require continuous engagement with study team to ensure high data quality and high levels of satisfaction

However, digital approaches must be balanced against data protection and privacy concerns.

RESULTS

- In 8 days of online study advertisement, 300 women signed up as being interested in participation
- Participants (n=66) were Swiss-residing women (mean age=27.5 years SD=4.1, range=19-36) and were recruited in 15 working days
- 92% of participants completed the minimum trial requirements (3 cycles) and 48.5% completed 6 cycles
- Participants (n=56, 85%) rated their experience with the social media recruitment (83%), online registration (98%) and online invitations (98%) as good or very good
- 61% of respondents considered the trial design easy or very easy to integrate into their everyday life, which might be correlated to the observed high compliance (87% of study days had all 3 procedures conducted)
- 64% preferred some personal contact with research staff, particularly during the onboarding process
- 98% of respondents found the study coordinator's remote support very helpful and 78% of participants were highly satisfied with the remote technical support



	Very good	Good	Neither good nor bad	Bad	Very Bad
Satisfaction with the study's social media recruitment	49%	34%	15%	2%	0%
Satisfaction with the study's online registration	43%	55%	0%	2%	0%
Satisfaction with the study's online invitation	54%	44%	2%	0%	0%

SUMMARY / CONCLUSION

- We demonstrated that using digital approaches for clinical studies leads to a high rate of completion (92%) and procedural compliance (87%), while maintaining participants' satisfaction (>90% reported their experience as good or very good)
- Site-less design could therefore help in maximizing clinical data collection while minimizing participants' burden
- Future studies with longer follow-up time will be needed to confirm our findings and assess whether the sampled population is biased towards digital natives. Moreover, digital approaches raise data protection and privacy concerns given the sensitivity of health data.
- Increasing the utilization of digital approaches in reproductive health research could increase the quality and the quantity of the data collected in this underrepresented research field