

PROMPT NIT-1: Setting up and implementing a multiple languages, multi-center PROMs survey

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Don't underestimate necessary efforts and resources for conducting an international multi-center, multiple languages study

BACKGROUND AND AIMS

- Aim: find out which PROMs work best for post-op pain assessment
- NIT-1 survey consists of several established tools
- Plan: include 1,000 patients for each of the 4 consented surgical procedures, collect data baseline, POD1, POD3, POD7, M1, M3 and M6

TASKS

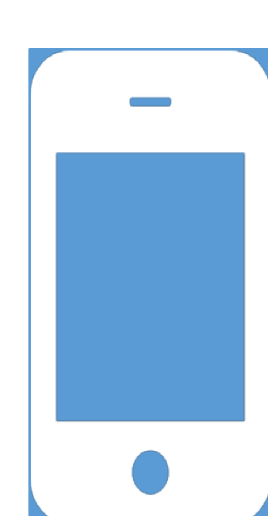
- Consent on questionnaires and questions
- Obtain all copyright permissions
- Translate survey into 8 languages
- Implement survey technically in all languages
- Recruit data collecting sites, conclude cooperation contracts
- Develop study protocol, patient information and informed consent forms and SOPs
- Register study in clinicaltrials.gov
- Obtain ethics approval in 18 data collecting sites across Europe, including GDPR clearance
- Train, support and closely monitor data collectors
- Remunerate data collectors

RESULTS

- 6 consortium and 12 non-consortium sites included 3,303 patients
- 6 out of 18 sites included considerably fewer patients than planned
- Sufficient case numbers for each procedure were reached
- Follow-up rates on M1, M3 and M6 are very good (70-80%)

CONCLUSION

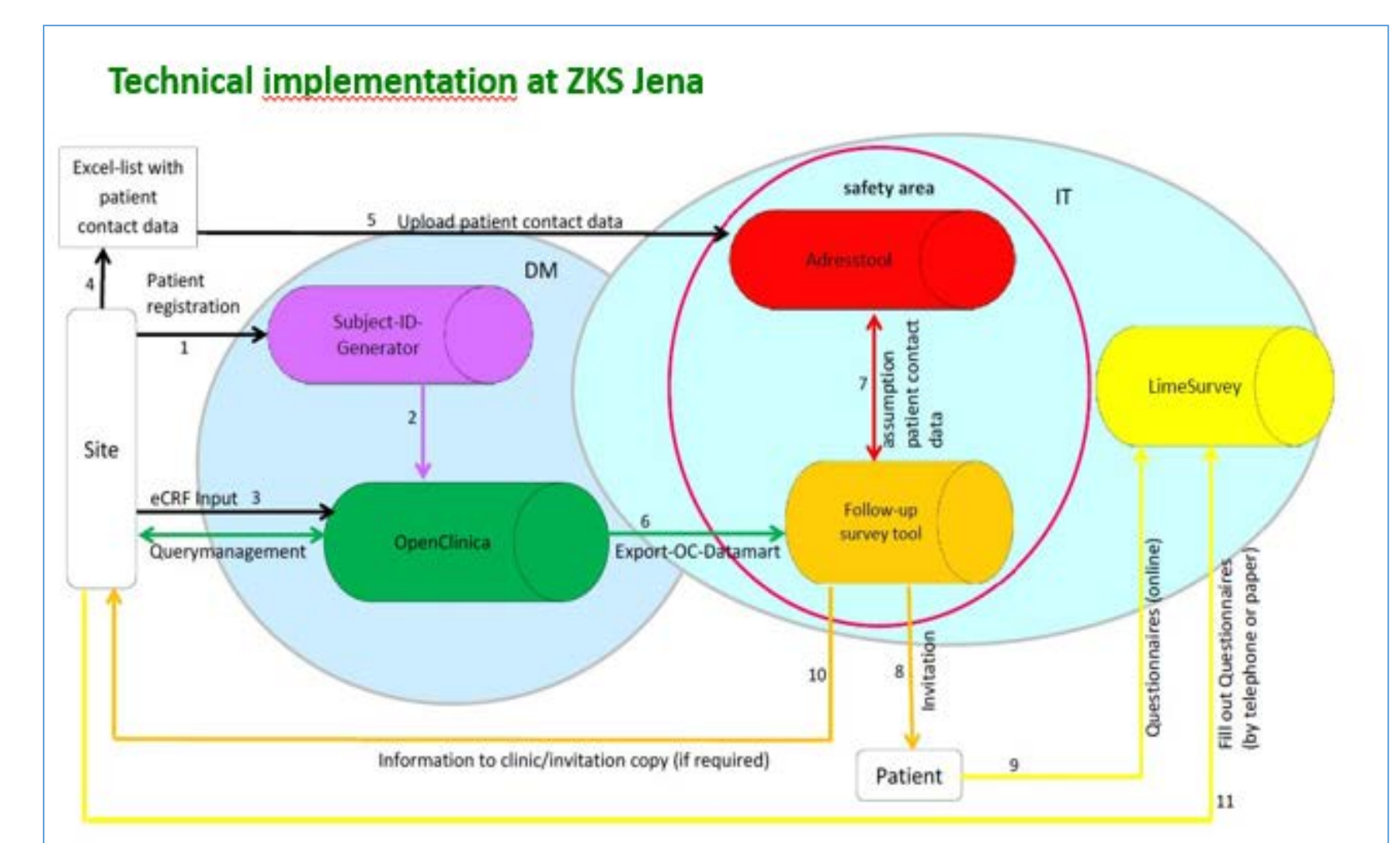
- Set-up and implementation of a large, international, multiple languages data collection is challenging and ambitious but feasible if sufficient resources (project management and technical expertise, qualified staff, funding, timeframe, commitment) are available



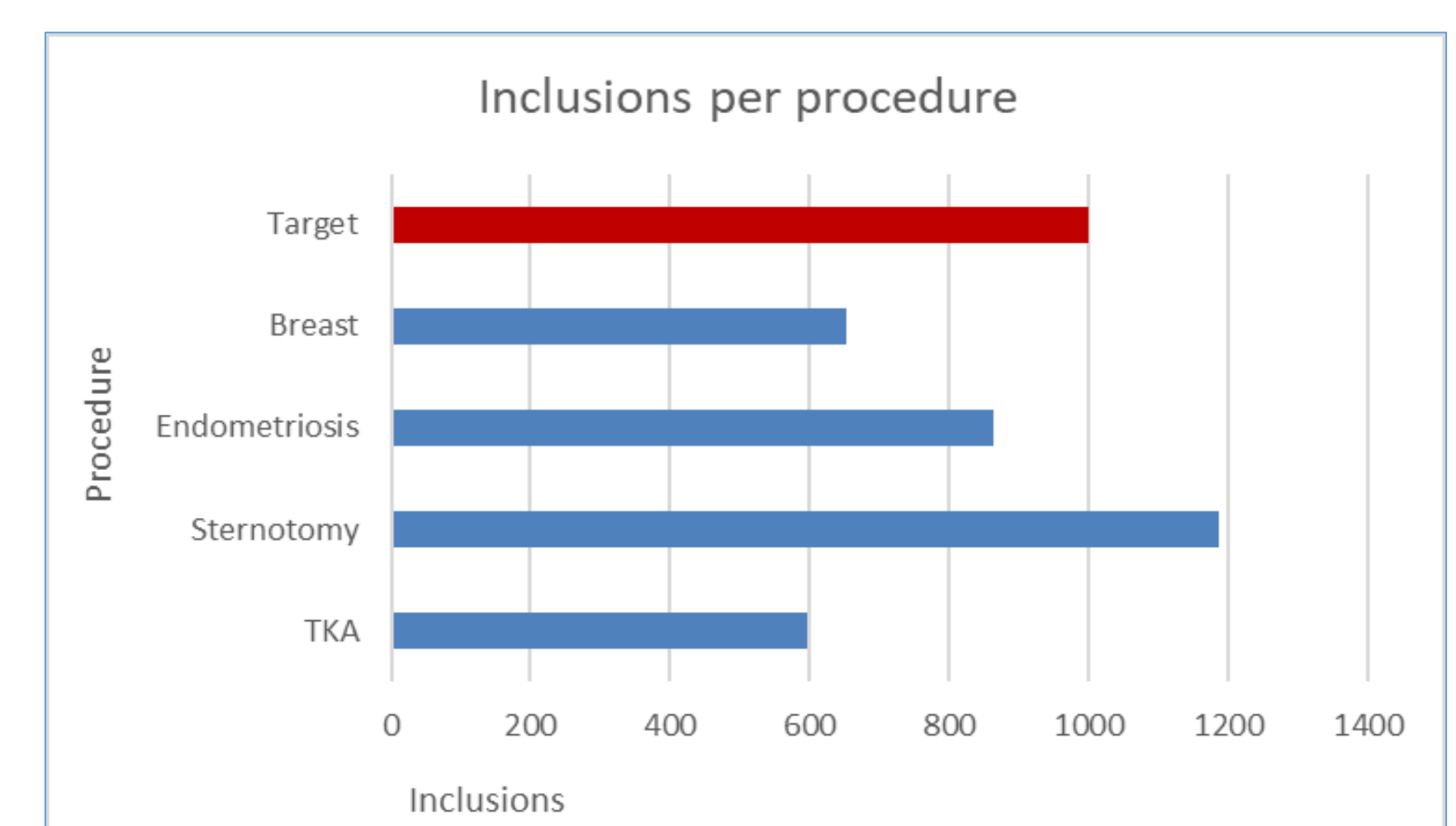
Take a picture for more information!



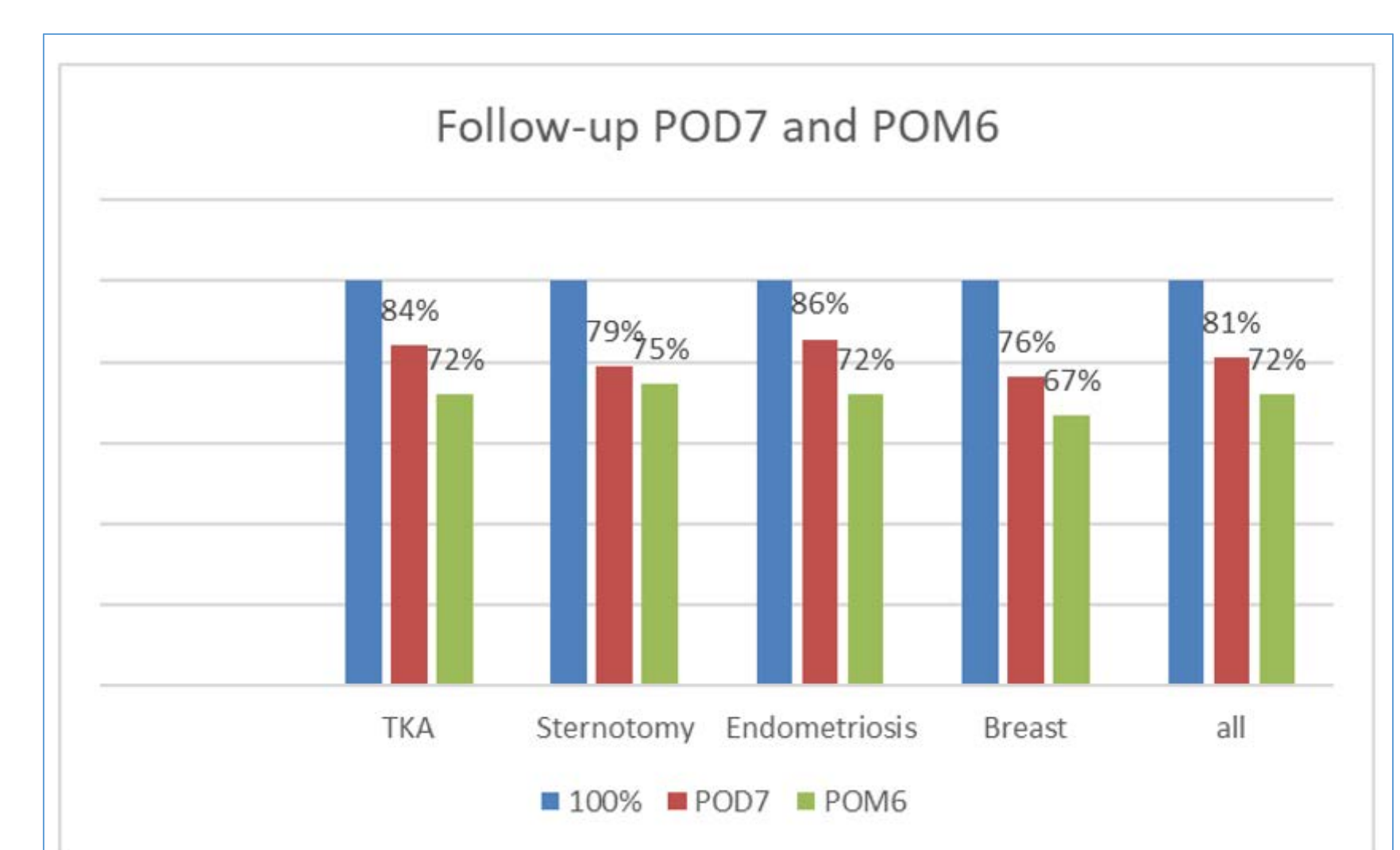
#1: Data collecting sites



#2: Technical implementation at ZKS Jena



#3: Inclusions per procedure at end of study



#4: Follow-up rates on POD7 and POM6