

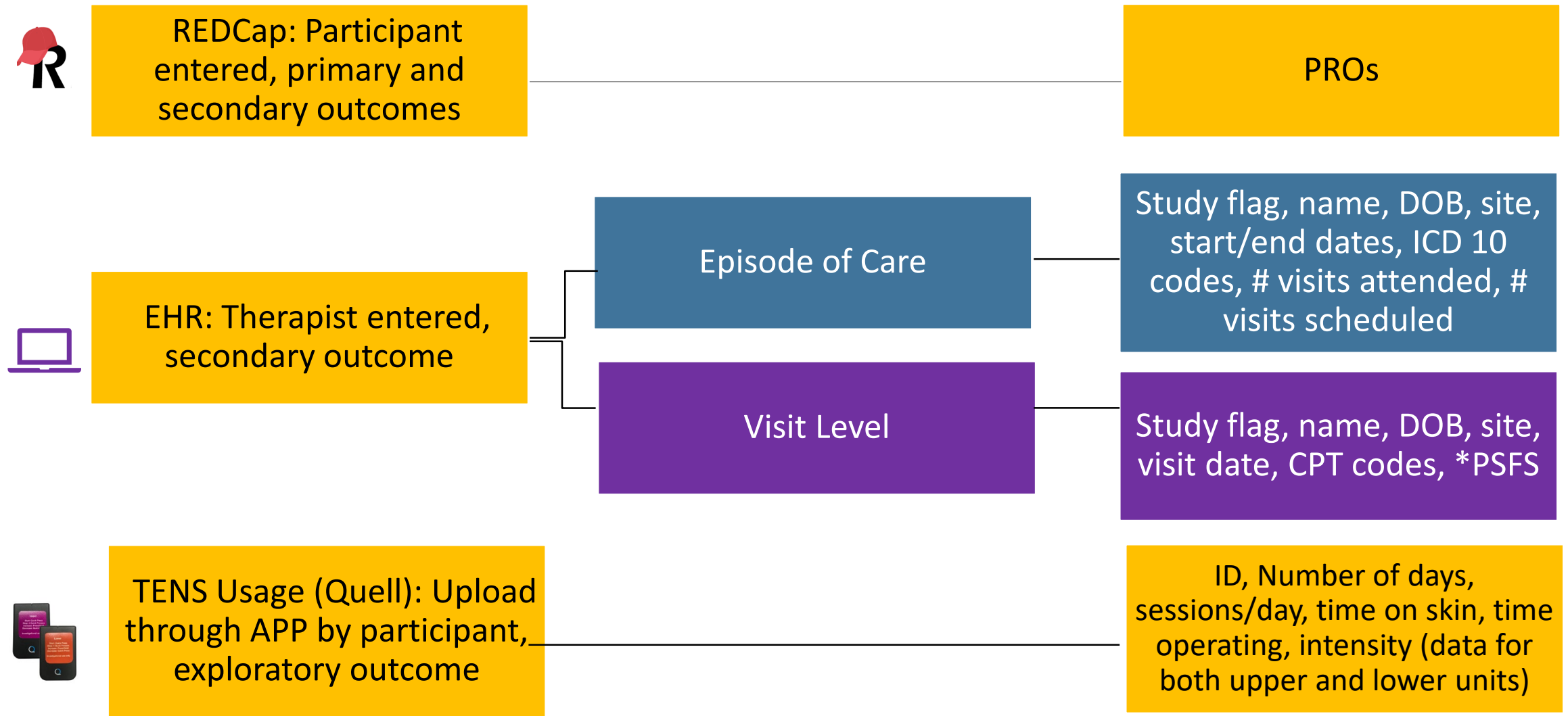
FM-TIPS Study Overview

The goal of FM-TIPS is to test the feasibility and effectiveness of adding transcutaneous electrical nerve stimulation (TENS) to standard physical therapy (PT) for individuals with fibromyalgia in a real-world physical therapy setting

- 25 active physical therapy clinics
 - 10 rural; 15 with ≤ 3 therapists
- 100+ physical therapists
- 5 active healthcare systems
- 11 EHRs

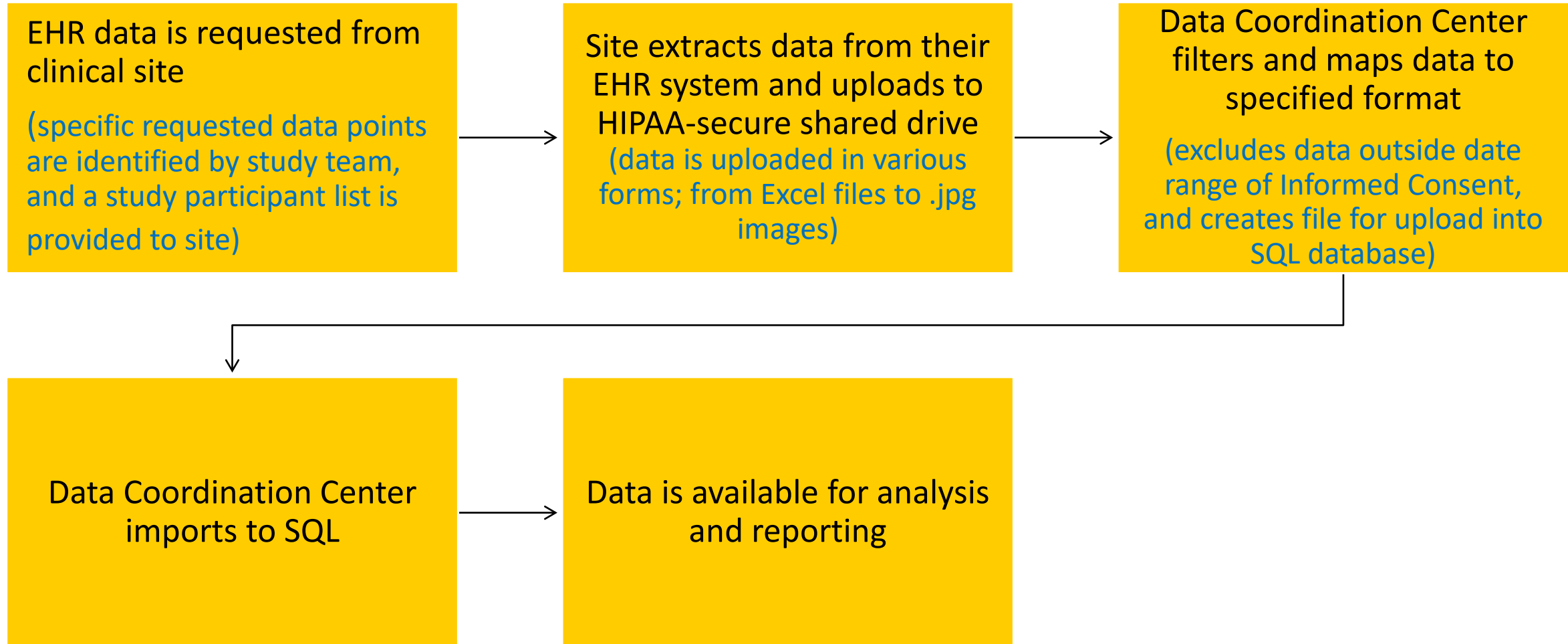


FM-TIPS Data Overview



*PSFS: Patient reported outcome measure initially done with therapist and moved to REDCap

EHR Data Flow



Challenges

- REDCap
 - Study “homework” done online
 - Population older, lower level of education/income
 - Issues with connectivity in ~25% of participants
- EHR
 - EHR system changes mid-study with access to old systems lost
 - Clinic personnel doing the data extraction
 - Difficult and costly to have EHR vendors run reports
 - Identifying some data elements problematic
 - Research participants not flagged
 - Episodes of care not matched to study period
 - Data most reliable when linked to billing (e.g. ICD 10 or CPT Codes)
 - Visit-level data most accessible
- Wearable device
 - Connectivity – TENS to APP, APP to internet
 - APP – Requires accurate set-up to match data to participant; data retention limits
 - Need advance planning for what data is required, difficult to go back



Lessons Learned

1

- Do your homework
 - Consult with sites/clinicians, biostatisticians and data managers in the study design phase
 - “Standard” EHRs (e.g., EPIC) and systems with professional data managers much more efficient for data extraction

2

- Sites/clinicians need support
 - Building relationships takes work
 - Focus is patient care, not research
 - Limited time, experience with data

3

- Data managers must be integrated during all phases of the study
 - Need to understand the data from all sources and how it will be collected, extracted, matched, cleaned and integrated