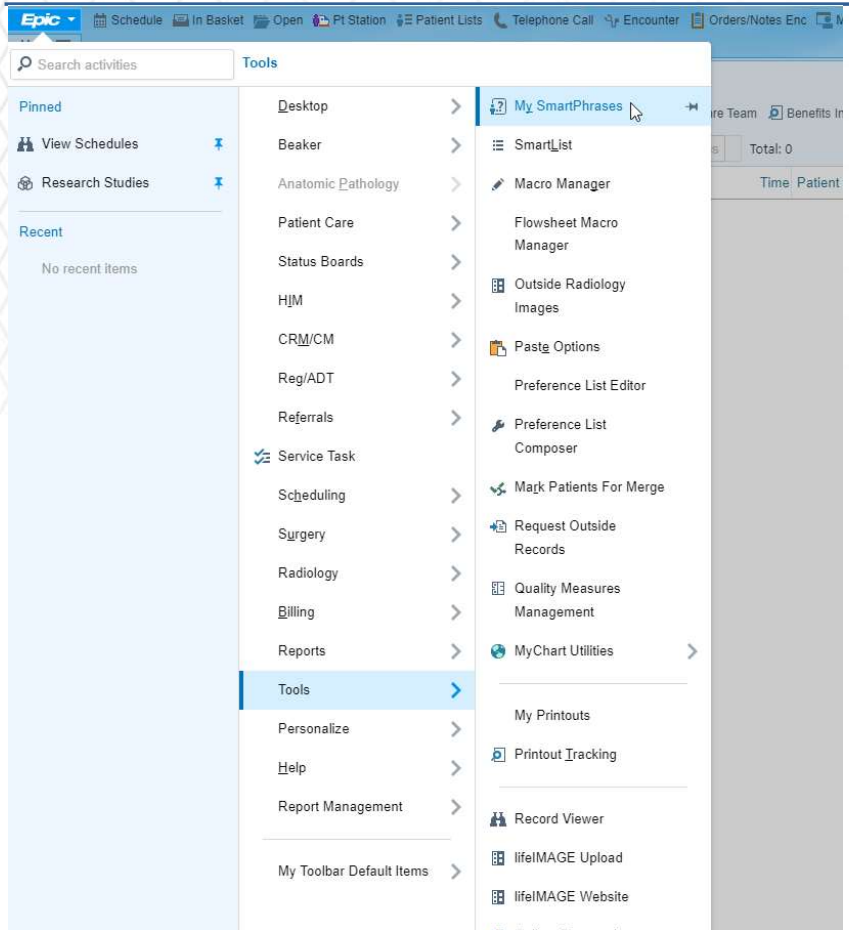
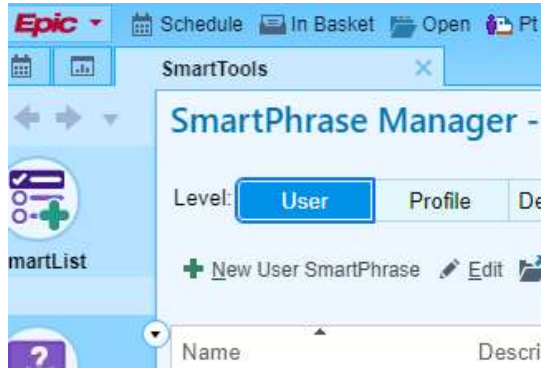
EMR Documentation

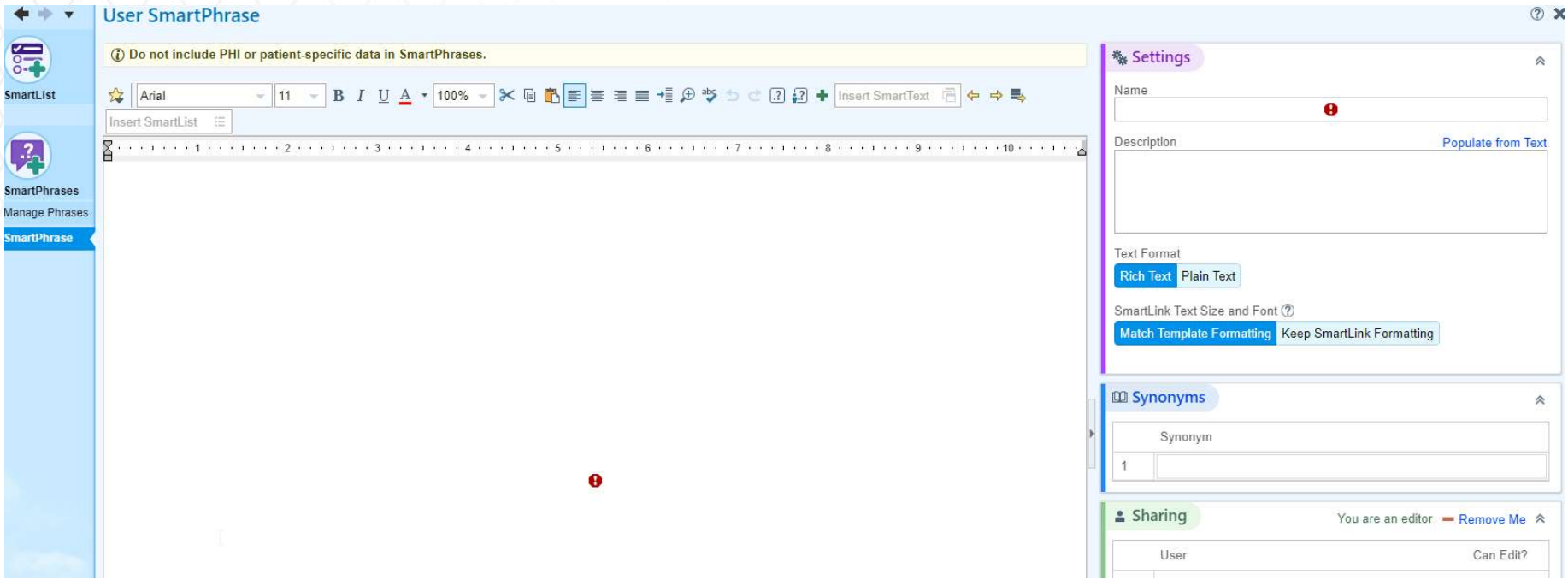
- Template notes in the EMR can help with documenting study visits
  - ICF consent process, visit details- history, medications, vitals, etc.
  - Should be study specific, following the schedule of events
- Template notes can be shared with team members who have charting abilities
- Easy documentation of PI oversight
- Helpful for non study care teams to know that patient is enrolled in a trial
- Linking the subject to a trial in the EMR enables notifications (e.g. safety events, new hospitalizations) to study team

How to create a template note in the EMR: EPIC





How to create a template note in the EMR: EPIC



Example of a template note

ASPIRE X Visit

Encounter Date: @ED@

Subjective:

@NAME@ is a @AGE@ {race/ethnicity:17218} @SEX@.

Research Protocol Title
Anticoagulation in Intracerebral Hemorrhage (ICH) Survivors for Stroke Prevention and Recovery (ASPIRE)

Research Number
UI# 201910203

Principal Investigator
Amir Shaban, MD

Informed Consent
Subject read the informed consent (Version 5.0, 01 Nov 2022). All concerns and questions were addressed. Consent was signed by the subject at XX:XX on XX/XX/XXXX, and this occurred prior to the study procedures being performed. Subject also consented for the ASPIRE Biobank sample collection (or state: Subject declined to also participate in the ASPIRE Biobank sample collection). A copy was given to the subject and a record of consent was placed in the medical record chart.

Chief Complaint (Select one of the following time points below)
Screening visit for the ASPIRE Trial. Inclusion and exclusion criteria for the ASPIRE Trial were reviewed.

Baseline/Randomization visit for the ASPIRE Trial.

Month X visit for the ASPIRE Trial.

Past Medical History:

@PROBSHORT@

@CMED@

Example of a template note

Medication Notes:
For screening visit use --> Mr./Mrs/Miss XXXX was screened for the ASPIRE trial. He/she will be randomized to study treatment on XX/XX/XXXX (or X months from now).

Randomization visit--> Mr/Mrs/Miss XXXX was enrolled into the ASPIRE Trial on XX/XX/XXXX. Today, he/she was randomized to the trial, and was dispensed kit XXXXXXXXXX, with bottle numbers XXXXXX and XXXXX. Mr/Mrs/Miss XXXX was provided with an ASPIRE Trial Alert Card, and this was reviewed with him/her. (or state It was verified that Mr/Mrs/Miss XXXX continues to have a ASPIRE Trial Alert Card). He/She was also provided with the Prohibited Medication list, Subject Information Sheet, and ASPIRE Medication Reminder form.

Monthly visits--> Kit XXXXXXX with bottle numbers XXXXX and XXXXX were dispensed on XX/XX/XXXX to Mr/Mrs/Miss XXXX, and they are being returned today. XX pills were dispensed in bottle XXXXXX, and XX are remaining. XX pills were dispensed in bottle XXXXXX, and XX are remaining.
Mr/Mrs/Miss XXXX was dispensed kit XXXXXXXXXX with bottle numbers XXXXX and XXXXX today.
It was verified that Mr/Mrs/Miss XXXX continues to have the ASPIRE Trial Alert Card.

Final or ET visit --> Kits XXXXXXX were dispensed on XX/XX/XXXX, and they are being returned today. XX pills were dispensed, and XX are remaining. The final dose of medication from this kit was taken on XX/XX/XXXX at XX:XX in clinic.

Adverse Events: Since signing the consent form, Mr/Mrs/Miss XXXX has not experienced any adverse events. (or choose - Since the signing the consent Mr/Mrs/Miss XXXX did experience XXXX. Chart when event occurred, if it was serious, required hospitalization, the severity, and any action taken. Note relationship to study related procedures).

Objective:
@VS@

Subject was sitting (or supine or standing) for the vitals

(Make sure to chart vitals at each visit including noting the time it was collected. Includes weight, HR, BP. Height only needed at screening)

Example of a template note

Assessment:

Study Assessments:

Bloods drawn at XX:XX for biosample collection. (done at screening only)

@GETLABS@

mRS = (List score and what it means)
Follow up form completed (at 3 months-on)
Montreal Cognitive Assessment completed (at 12 months)
PROMIS Global Health form completed (at 12 months)
PROMIS Emotional Distress Anxiety form completed (at 12 months)
PROMIS Emotional Distress Depression form completed (at 12 months)
Short IQCODE was completed by (state NOK of subject who completed it). (at Baseline only)

Plan:

Plan: Mr/Mrs/Miss XXXX will be return to clinic on XX/XX/XXXX (or state: in X months from now) for the baseline/randomization visit for the ASPIRE Trial.

Mr./Mrs./Miss XXXX will return to clinic in 3 months for the next clinic visit for the ASPIRE Trial.

Staff Physician Comments:

Counseling/Coordination of Care:

@ME@