Program Director/Principal Investigator (Last, First, Middle):

PROJECT SUMMARY (See instructions):

Improving clinical trial efficiency by leveraging known medication information

The efficiency of clinical trials is a problem of national security for the United States, which largely failed during the COVID pandemic to quickly establish clinical care guidelines, resulting in excess mortality. A major flaw of existing clinical trial methodology is that enrolled patients' pre-existing medications can lead to adverse effects, but such information is not easily accessible to clinicians. Issues of interoperability have largely prevented clinical trial technologies from integrating with medication information databases. These databases have been extensively used and vetted in clinical informatics research. Recent advances in data interoperability enable such methods to be applied in a clinical trial use case. Our team has patients' medication lists from a real clinical trial, domain expertise in clinical trials, and experience in developing user-friendly software tools. We present a plan with the following specific aims.

1) To automatically relabel miscoded medication information for clinical trial patients.
2) To leverage established public databases to capture and visualize information about patients' medication usage at various levels of abstraction for clinical trial investigators.
3) To report known side effects of patients' current medications to improve adverse event reporting in clinical trials.

We will evaluate success by testing tool performance and robustness on an unseen clinical trial dataset. With this tool, clinical trial reporting practices will be improved by better incorporating medication information.

RELEVANCE (See instructions):

Improving clinical trial efficiency is crucial for the health and security of U.S. citizens. A great deal of information about medication side effects is available in public databases, but is not readily accessible by clinicians. We will develop a tool to report relevant medication information to improve patient monitoring and analysis, thereby raising patient safety standards in translational medicine.

PROJECT/PERFORMANCE SITE(S) (if additional space is needed, use Project/Performance Site Format Page)

Project/Performance Site Primary Location		
Organizational Name:		
DUNS:		
Street 1:	Street 2:	
City:	County:	State:
Province:	Country:	Zip/Postal Code:
Project/Performance Site Congressional Districts:		

Additional Project/Performance Site Location		
Organizational Name:		
DUNS:		
Street 1:	Street 2:	
City:	County:	State:

Province:	Country:	Zip/Postal Code:
Project/Performance Site Congressional Districts:		

SENIOR/KEY PERSONNEL. See instructions. *Use continuation pages as needed* to provide the required information in the format shown below. Start with Program Director(s)/Principal Investigator(s). List all other senior/key personnel in alphabetical order, last name first.

Name	eRA Commons User Name	Organization	Role on Project
Bryan Bunning		Stanford University	Co-Investigator
Karen Feng		Stanford University	Co-Investigator
Holly McCann		Stanford University	Co-Investigator

OTHER SIGNIFICANT CONTRIBUTORS

Name	Organization	Role on Project

Human Embryonic Stem Cells ☐ **No** ☐ **Yes**

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://stemcells.nih.gov/research/registry/eligibilityCriteria.asp. *Use continuation pages as needed.*

If a specific line cannot be referenced at this time, include a statement that one from the Registry will be used.

Cell Line