



SCCR Clinical Endpoint Classification (CEC) Committee

Standardization of clinical outcomes reporting for global clinical trials

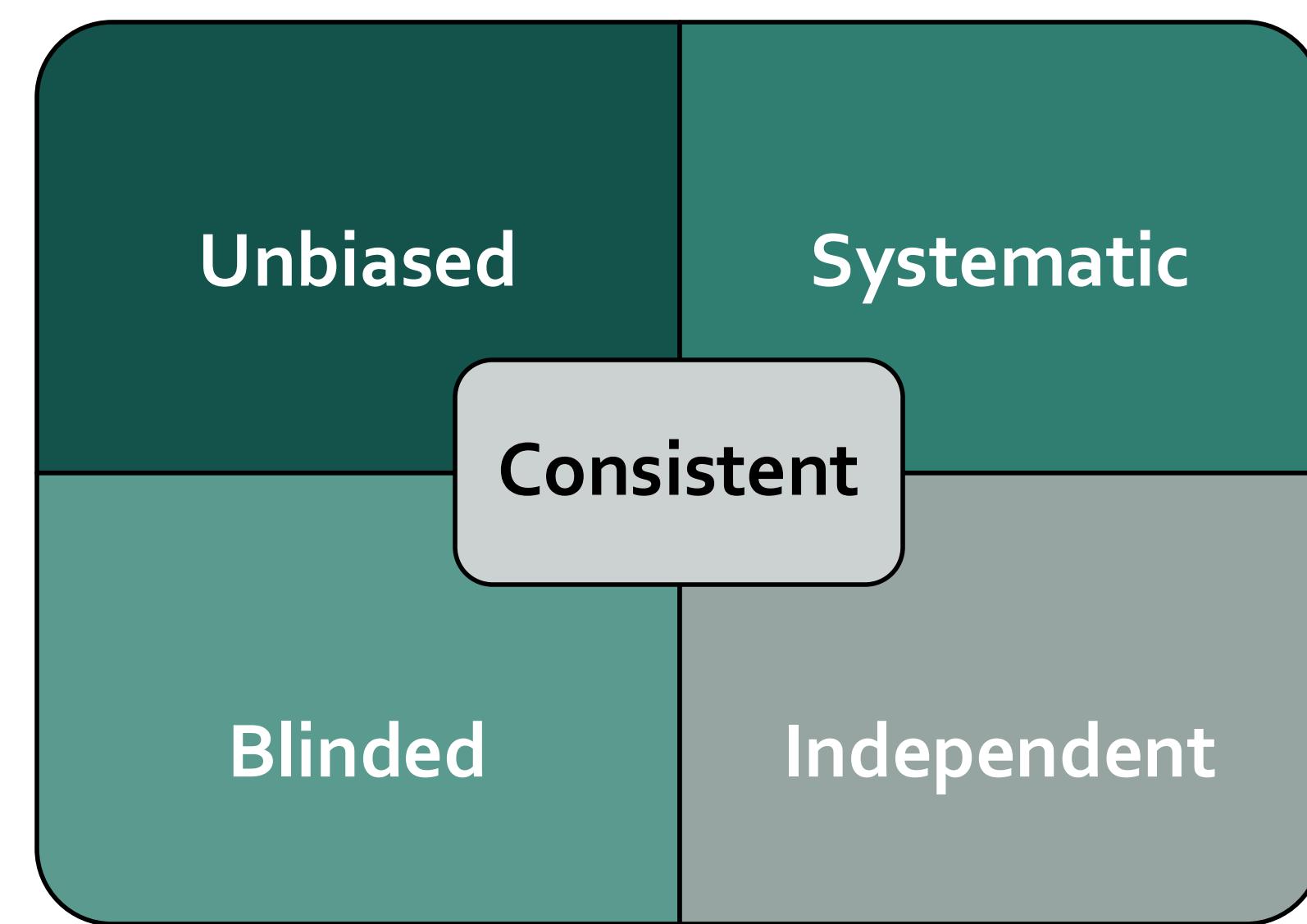
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WHAT IS CEC?

Clinical Endpoint Adjudication is an important feature of large, randomized clinical trials.

Independent endpoint adjudication is used to systematically classify clinical outcomes in clinical trials in an unbiased way. SCCR faculty and operations staff have extensive experience in clinical endpoint adjudication; they have led event adjudication in over 210 clinical trials with over 115,000 endpoints adjudicated.



The SCCR CEC operations team and faculty physician adjudicators have resources and clinical expertise to provide comprehensive adjudication services in all phases of development.

PARTNERS AROUND THE WORLD

Academic Partners



External Partners



ACKNOWLEDGEMENTS

Kevin Alexander
Faculty Associate Director,
CEC

Ken Mahaffey
Director of SCCR

SCCR CEC WEBSITE

<https://domsccr.stanford.edu/>

SCCR CEC TEAM

Jill Marcus, CEC Project Manager
Nicole Greer, CEC Coordinator
Kim Clinton, CEC Coordinator

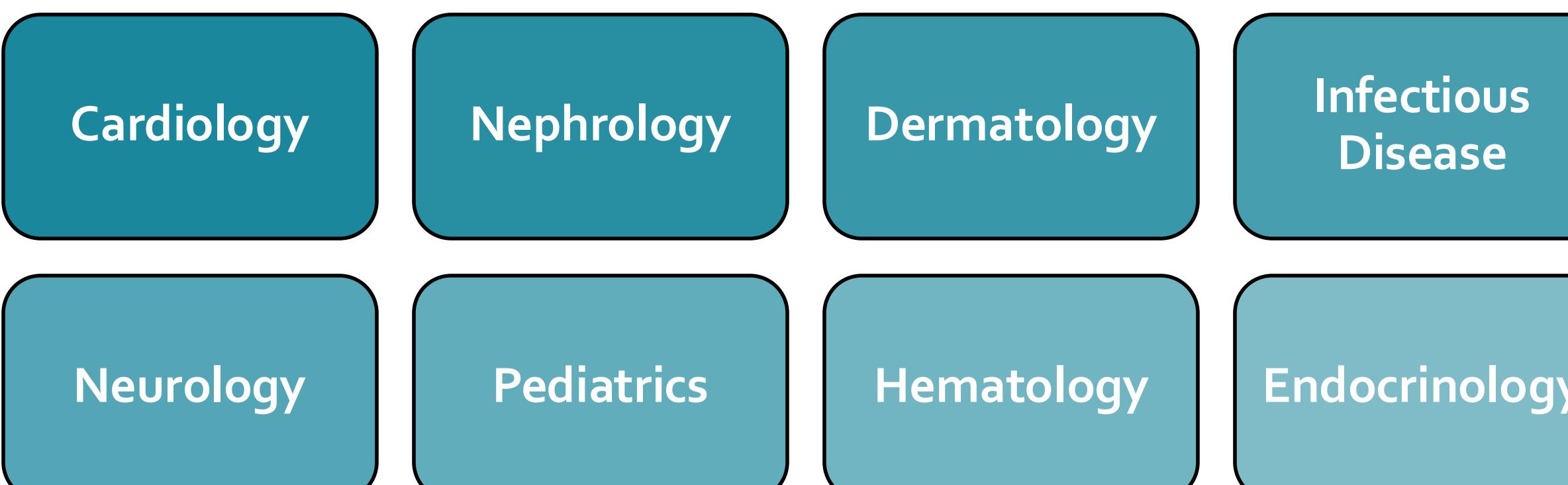
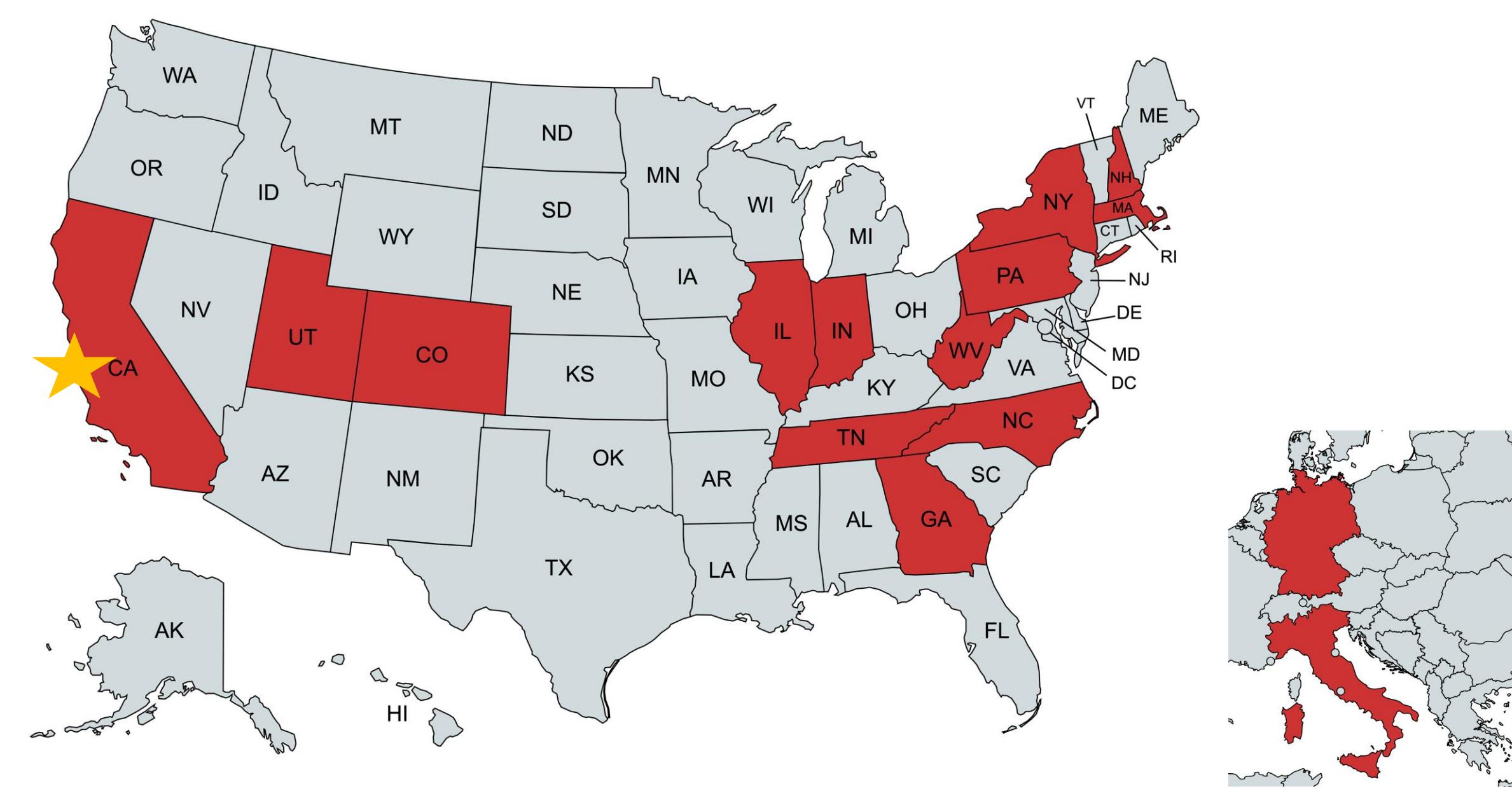
WHY IS ADJUDICATION IMPORTANT?

CEC is an independent and unbiased committee made up of Physician Reviewers with therapeutic area expertise who systematically and consistently apply pre-defined event definitions to adjudicate clinical endpoints. Clinical endpoints are outcome measures of the occurrence of disease or symptoms within a target population in a clinical trial. Adjudication processes and event definitions are documented in the CEC Charter. The CEC committee functions independently from sites and sponsors to objectively measure clinical outcomes that characterize the safety and efficacy profile of an investigational drug or device.

The adjudication process is key to the measurement of clinical outcomes in pivotal clinical trials. CEC employs a method of event classification that significantly reduces variability in clinical event reporting across sites, investigators and geographic regions. This approach standardizes the classification and reporting of clinical endpoints and strengthens the overall quality of the data set. The adjudication results are used in the final analyses of clinical trials to establish whether trial objectives were met, which regulatory authorities consider when reviewing regulatory submissions.

NETWORK OF SCCR ADJUDICATORS

Our broad network of adjudicators across the US & Europe has expertise in various therapeutic specialty areas. The CEC operations team supports and manages CEC processes and adjudication under the leadership of Dr. Ken Mahaffey and Dr. Kevin Alexander.



SCCR CEC PORTFOLIO

The SCCR CEC team provides the following capabilities:

- CEC charter development with endpoint definitions
- Clinical Database Endpoint case report form development
- Adjudication form development
- Development and execution of CEC Project Management Plan

- Training of study site investigators and staff, and adjudicators
- Management of electronic adjudication platforms
- Quality control procedures
- Partners with Data Management

