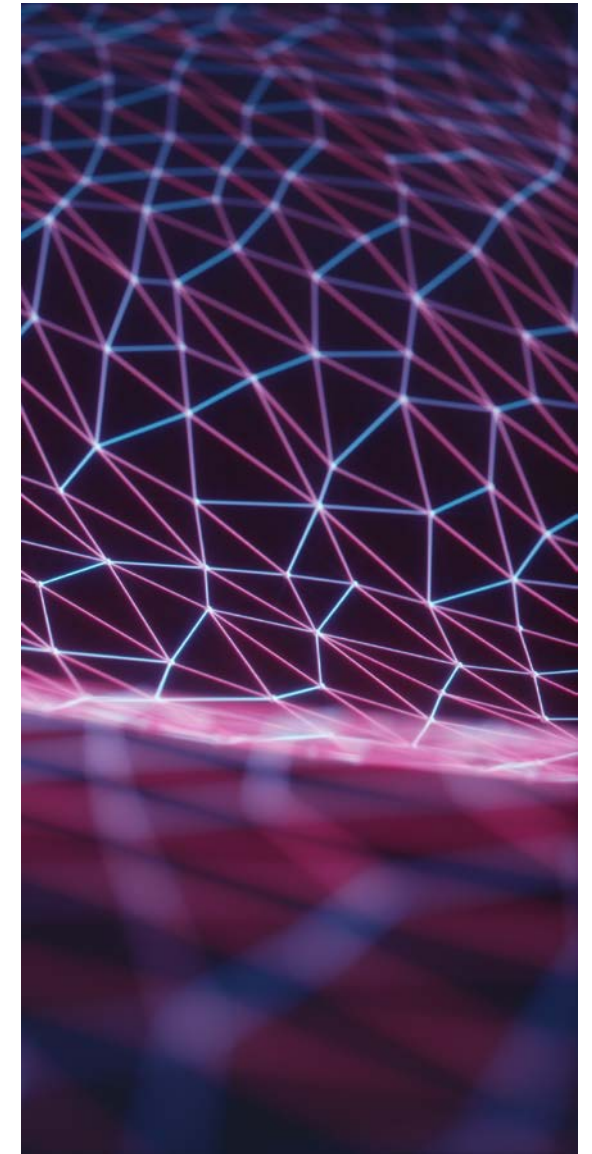


# Contracting Work Group

Erick Jenkins, UCOP

Tam Tran, UCI

October 3, 2018



# Variety of Achievements in 2017 - 2018

- Increasing Master Agreements
  - UC Master CTA Prioritization
  - ACTA Metrics Project
- Investigator Initiated Trials Toolkit
- Contract Rationales Project
- FY '18-19 Plans



# CWGW 2017-18 Members

- Erick Jenkins, UC Davis
- Tam Tran, UC Irvine
- Helene Orescan, UC Los Angeles
- Lauren Sanfilippo, UC San Diego
- Kent Iwamiya, UC San Francisco
- Andrew Jones, UC Office of the President
- Glennia Campbell, Stanford University



# About the CWG

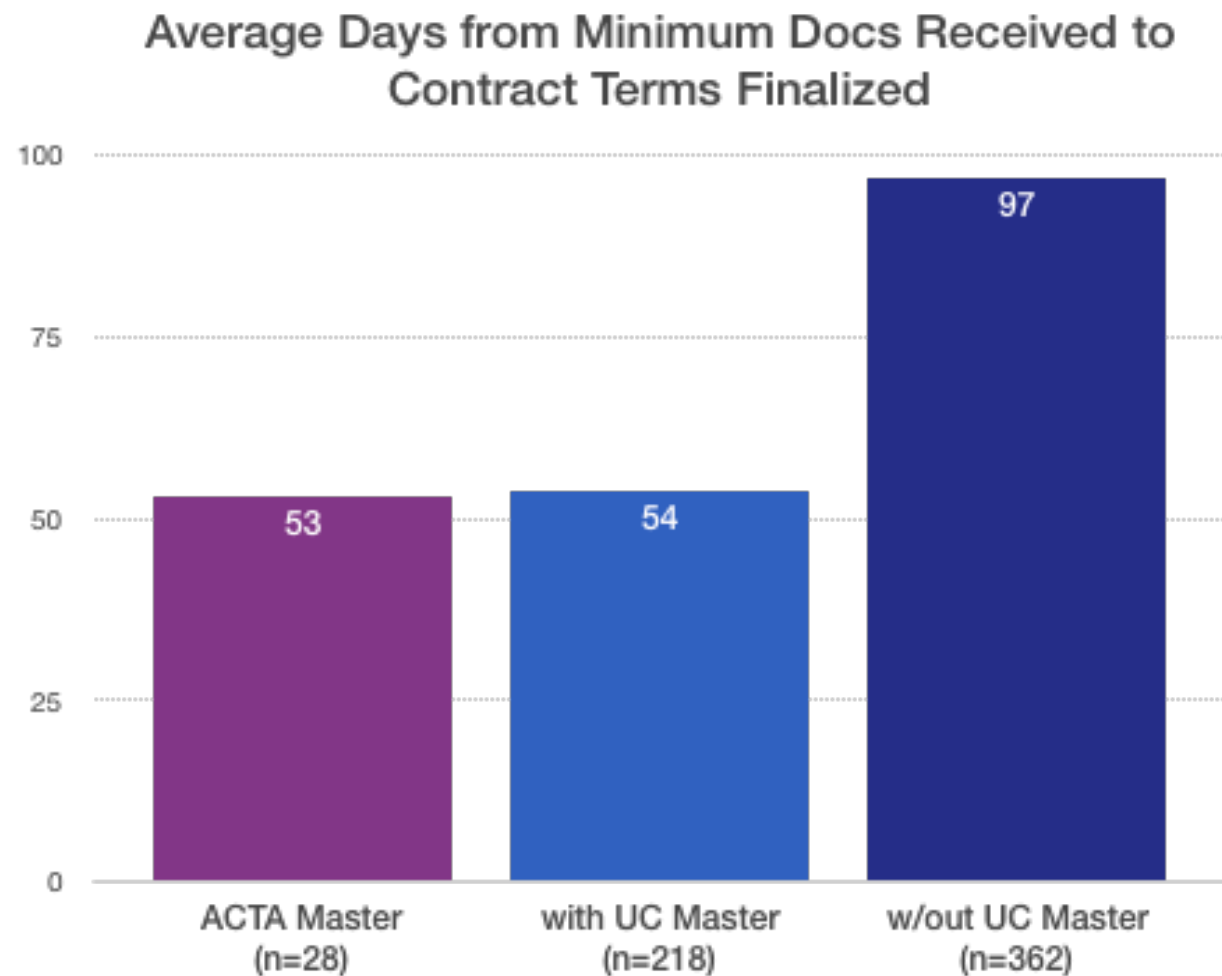
- The Contracting Group has been active at UC BRAID since 2013
- **Goals:**
  - Measure and improve clinical trial contracting performance
  - Share best practices and lessons learned
  - Increase collaboration for multisite clinical trial agreement (CTA) negotiations
  - Mitigate redundant effort

# UC Master CTA Prioritization

- Current UC Master Agreements
  - 26 CTAs
  - 9 CDAs
- Prioritized sponsors for new agreements:
  - Sponsor-initiated trials
    - 1) Janssen
    - 2) Celgene
    - 3) Boehringer / Millennium-Takeda
  - Investigator-initiated trials
    - 1) AstraZeneca
    - 2) Merck & Bristol-Myers Squibb [tie]

# ACTA Metrics Project

- Both Accelerated Clinical Trial Agreements (ACTA) and UC Master CTAs were 45% faster compared to contracts which did not use a master agreement



# Investigator Initiated Trials Toolkit

- BRAID web resource: Improving Investigator Initiated Trial Contracting Efficiency
- Best practices to streamline contract negotiation
- All 5 UC campuses link to the tool
- Publicized via CTSA hubs



## Announcements

**UC BRAID**  
innovation-collaboration-acceleration

[ICTS Community Engagement Studio](#)

Investigator Initiated Trials (IITs) may encounter pitfalls leading to study delays. The UC BRAID collaborative has developed a set of webpages intended to provide guidance on the information needed when starting an IIT to facilitate efficient contracting and move the trial forward as quickly as possible. Each page highlights information about elements of the study, questions that the contracting office will need answered, or checklist items for the PI to accomplish. [Web tool for Investigator Initiated Trials \(IITs\)](#).

For additional support visit the UCI Office of Research [Starting Point](#).

The ICTS is pleased to announce a new call for Community Engagement Studios Awards. Recipients of the award will have CE Studio-trained ICTS administrators plan, organize, conduct, and follow-up a personalized CE Studio for any study in which community input could inform improvements in the study (or grant proposal) development, design, recruitment, retention, and/or dissemination activities: [Community Engagement Studio Award](#).

[Apply Today!!](#)

# Contract Rationales Project

**Need:** A comprehensive rationales resource to streamline negotiation with sponsors

**Solution:** Created a shared compendium of rationales used during redlining of CTAs

- Summaries of UC positions
  - Legal, Policy, and Operational
- Identified 19 key areas
  - e.g., indemnification, subject injury, inventions



# Next Steps: FY '18-19 Plans

- CTA Contracting Streamlining Pilot b/w UC Davis and UC Irvine
  - Streamline CT contracting; understand campus tolerance for risk, etc.
  - Create consistency of terms across UC campuses
  - Increase the volume and types of studies across the UCs
  - Appeals to sponsors
  - Greater collaboration among campus departments and contracting offices
  - Reduced FTE time and complexity for relying campuses
  - Create an easy to use agreement review tool for contract collaboration

# CWGW 2018-19 Members

- Valerie Ody, UC Davis
- Tam Tran, UC Irvine
- Tamika Merrick, UC Los Angeles
- Maria Rutecki, UC Los Angeles
- Sanaz Masha, UC San Diego
- Tanya Wei, UC San Francisco
- Erick Jenkins, UC Office of the President
- Andrew Jones, UC Office of the President
- Glennia Campbell, Stanford University

