ADCS Virtual Town Hall

October 13, 2021
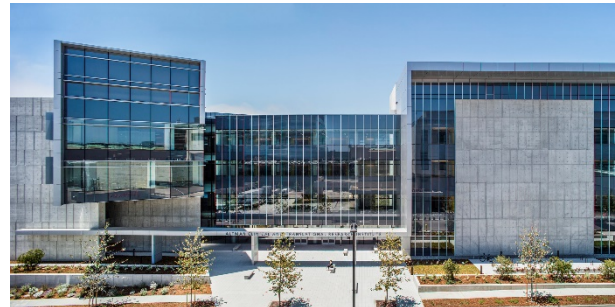
AGENDA

Topic	Presenter(s)
1. Welcome and COVID-19 Updates	Howard Feldman
2. Data Management Presentation	Jen Mason, Sean Kipperman, Kevin Zielin, Lorena Naylor for the ADCS Data Management Team
3. Administrative Updates	Carol Evans
4. Questions/Comments	All
5. Walk-in Items	All

Congratulations!

Dr. Andrea LaCroix

Winner: 2021 UC San Diego Health Sciences Faculty Excellence in Mentoring Award

Celebrating Health Sciences faculty who have demonstrated significant commitment to **inclusive mentorship** of junior faculty, residents, fellows, postdoctoral scholars and/or students -- particularly to mentees from groups underrepresented in academic medicine and the sciences
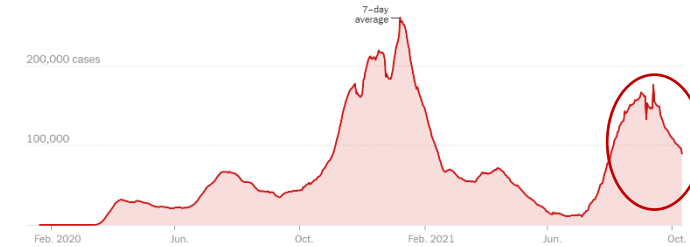
COVID-19 Update

Dr. Howard Feldman

USA Pandemic Update National and Local: as of October 12, 2021

- **COVID-19 cases nationally**
  - US: 44.5 million+ cases, 714,960 deceased
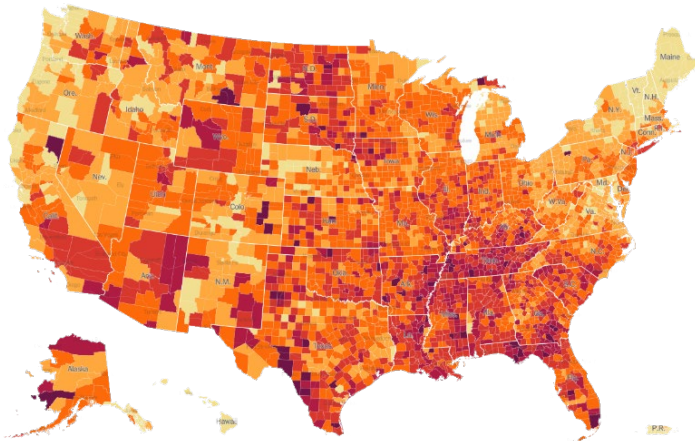 - An average of 89,526 cases/day, **24%** decrease from the average two weeks earlier

United States Avg. on Sept. 13	14-day change		United States Avg. on Sept. 27	14-day change		United States Avg. on Oct. 11	14-day change
New cases 172,404	+8%		New cases 117,966	−33%		New cases 89,526	−24%
New deaths 1,827	+36%		New deaths 2,052	+12%		New deaths 1,853	−10%
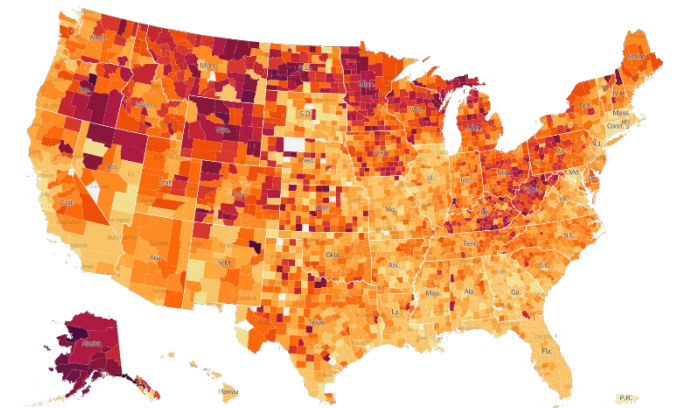
New York Times Published on: September 14 & 28, October 12, 2021

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As of October 12, 2021 – California Counties on Monitoring List

https://covid19.ca.gov/safer-economy/

Track county data and monitoring status

San Diego County risk level: High Orange

As of 10/12/2021

Statewide Metrics

12.2
New COVID-19 positive cases per day per 100K

2.1%
Positivity rate

San Diego County Metrics

13.1
New COVID-19 positive cases per day per 100K

2.6%
Positivity rate

As of 09/28/2021

Statewide Metrics

16.4
New COVID-19 positive cases per day per 100K

2.5%
Positivity rate

San Diego County Metrics

16.4
New COVID-19 positive cases per day per 100K

2.9%
Positivity rate

As of October 12, 2021

VACCINES ADMINISTERED
50,679,798 total
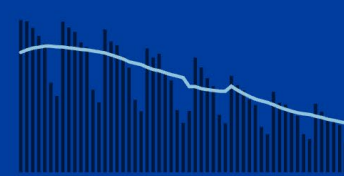86,481 daily avg.
79.4% of population vaccinated
Past 8 weeks

CASES
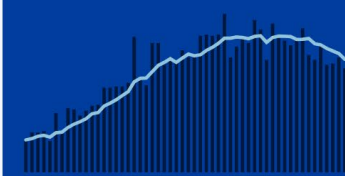4,557,285 total
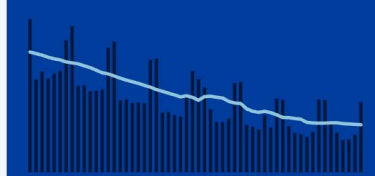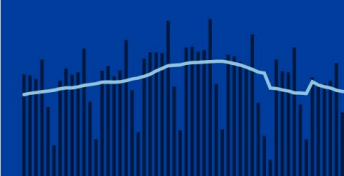5,121 daily avg.
12.2 new cases (per 100K)
Past 8 weeks

DEATHS
69,756 total
88 daily avg.
0.2 new deaths (per 100K)
Past 8 weeks

TESTS
2.1% test positivity
Past 8 weeks

As of September 28, 2021

VACCINES ADMINISTERED
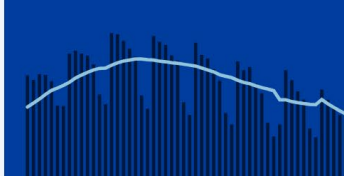49,186,995 total
71,394 daily avg.
78.1% of population vaccinated
Past 8 weeks

CASES
4,476,388 total
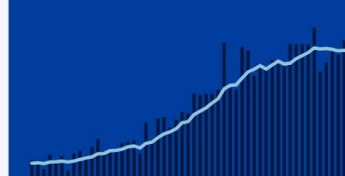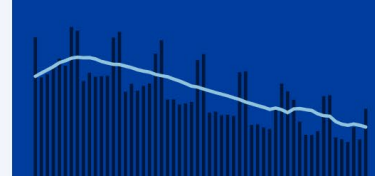7,017 daily avg.
16.4 new cases (per 100K)
Past 8 weeks

DEATHS
68,387 total
100 daily avg.
0.2 new deaths (per 100K)
Past 8 weeks

TESTS
2.5% test positivity
Past 8 weeks

ADCS COOPERATIVE STUDY   UC San Diego SCHOOL OF MEDICINE

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San Diego County COVID-19 Watch

Figure 1. COVID-19 Confirmed and Probable Cases and 7-Day Rolling Average Case Rate by Date of Illness Onset*, San Diego County Residents, N=79,494

Since July 4, 2021:
Confirmed N=74,305
Probable N=5,189

Data for this period may be incomplete.

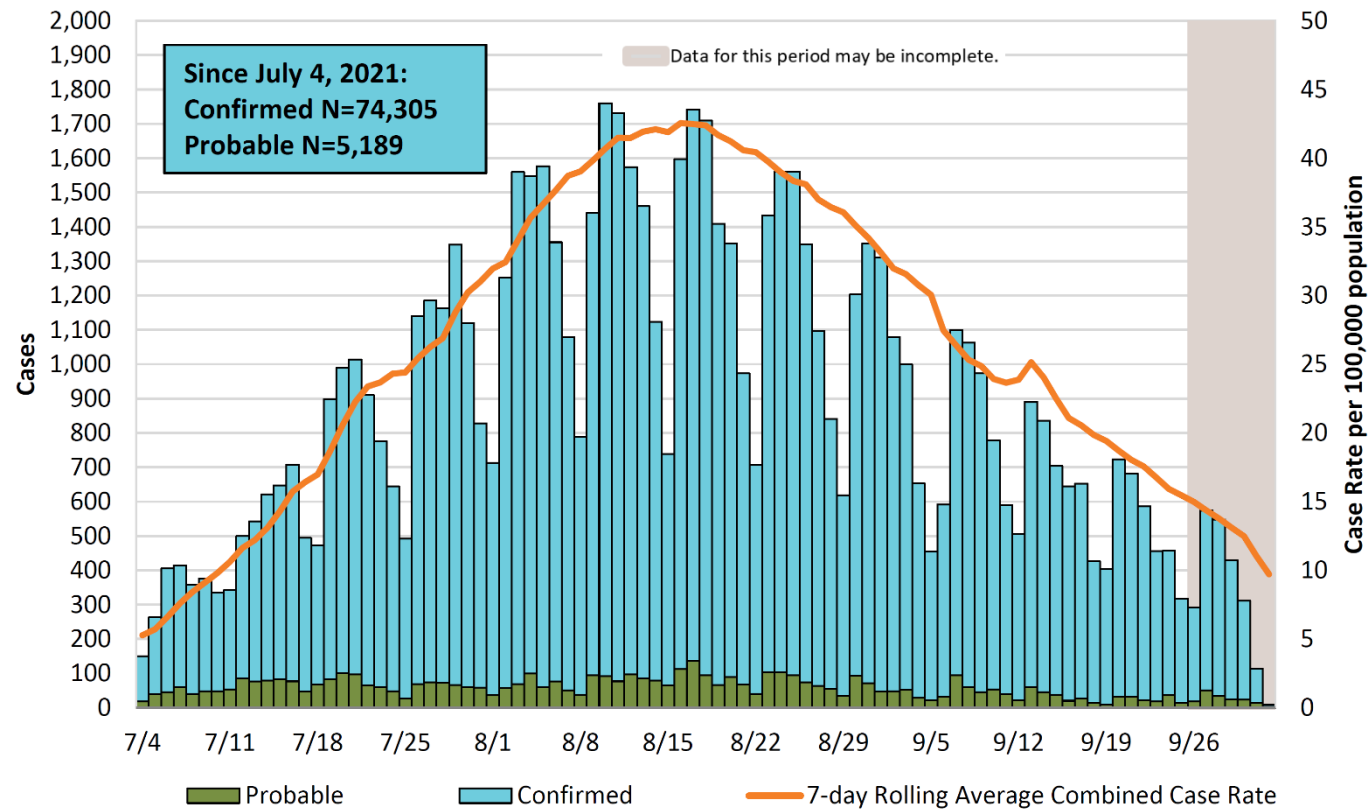Legend: Probable | Confirmed | 7-day Rolling Average Combined Case Rate

Table 1. Summary of Cases, Deaths, and Outbreaks by Date Reported

|	9/26 – 10/2/2021	9/19 – 9/25/2021	Cumulative
Cases	3,667	5,158	358,108
Avg Daily Cases	524	737	624
Deaths	30	45	4,081
Outbreaks	39	45	2,779

Surveillance Report – October 6, 2021

San Diego County COVID-19 Watch

Hospitalization rate for not fully vaccinated residents is **23 times higher** than fully vaccinated residents

Dates: 9/5-9/11/2021

Not Fully Vaccinated* Hospitalization Rate	Fully Vaccinated ** Hospitalization Rate	County Overall Hospitalization Rate
1.15	**0.05**	**0.51**

Figure 3. 7-Day Rolling Average COVID-19 Hospitalization Rate by Vaccination Status in San Diego County Residents since March 1, 2021
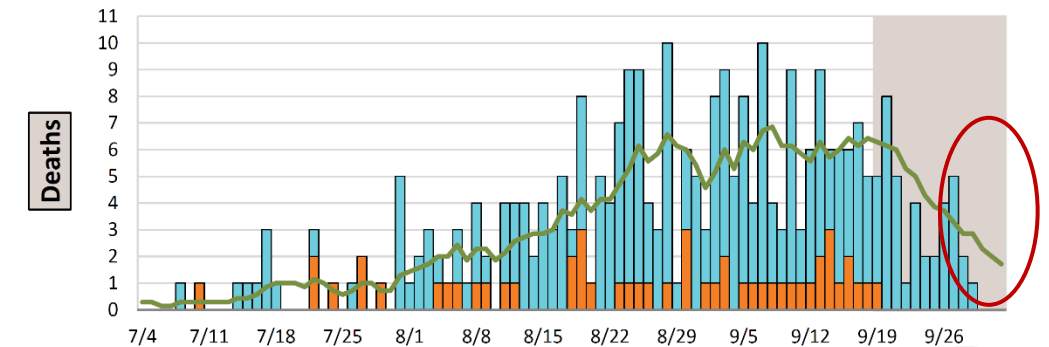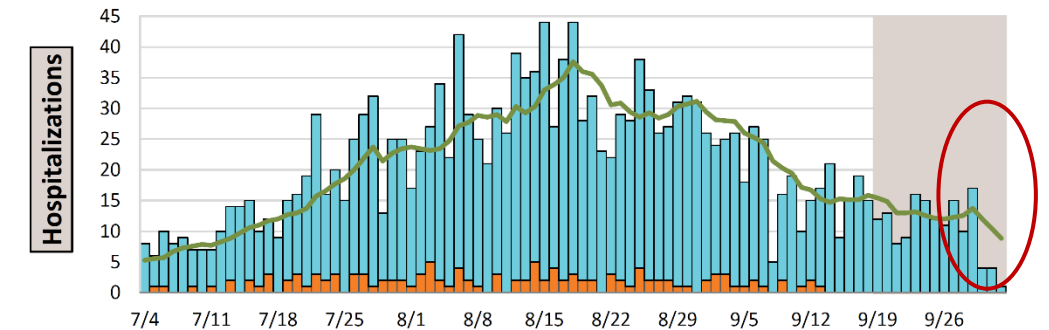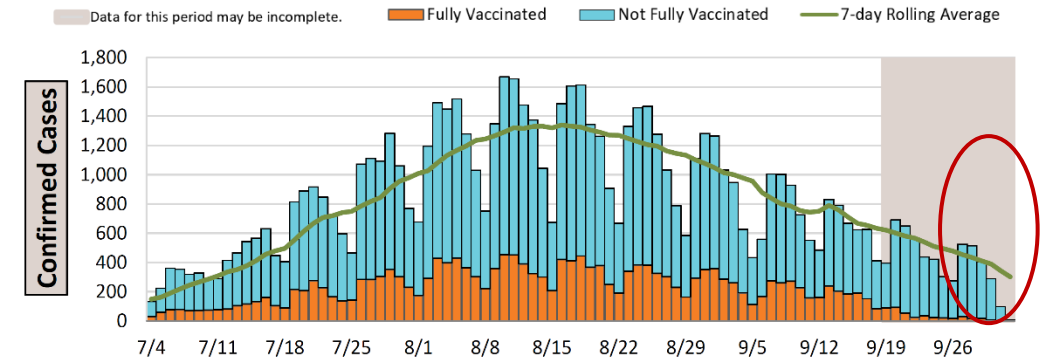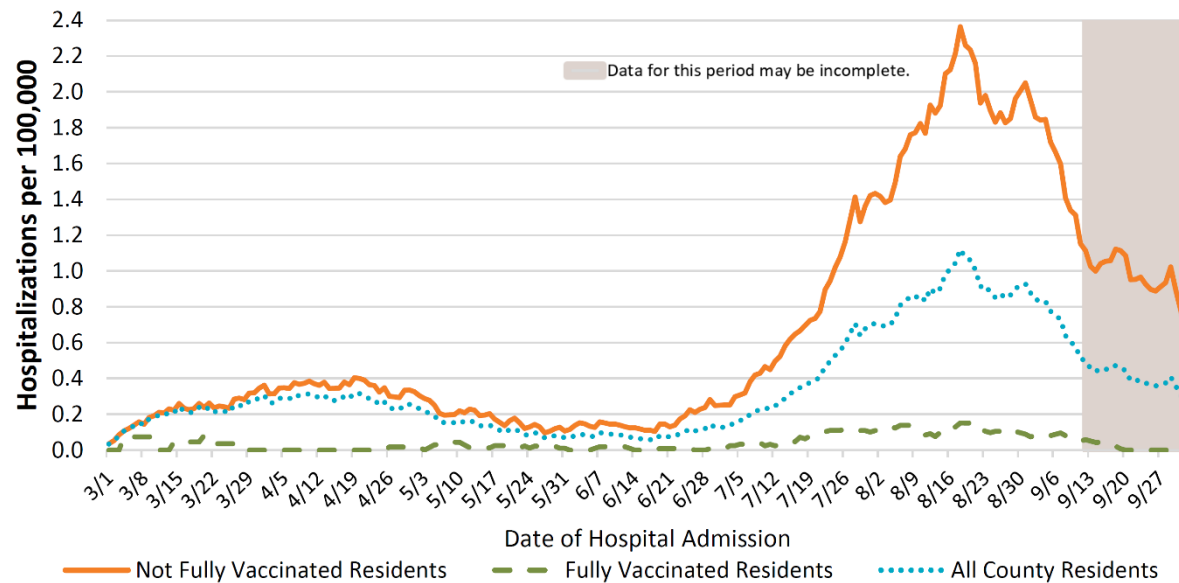
UCSD Health
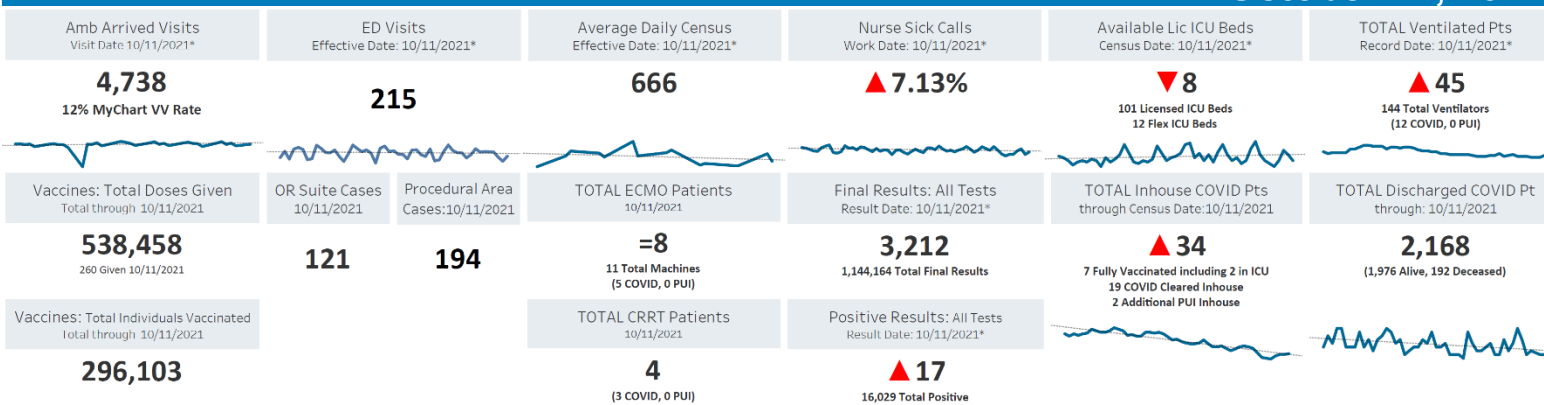
COVID Admits 34
COVID Ventilators 12
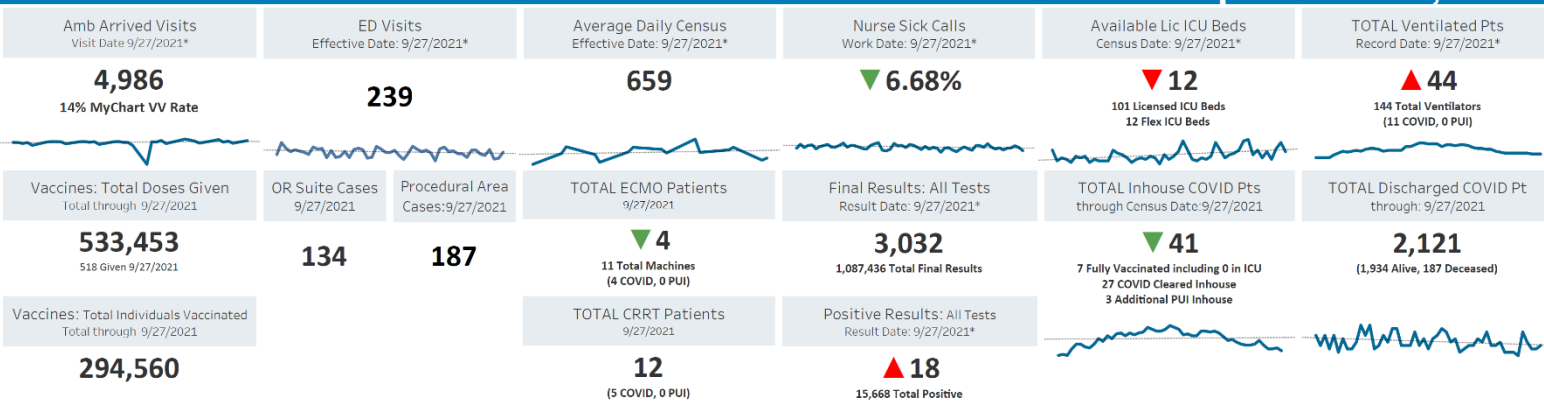
COVID Admits 41
COVID Ventilators 11
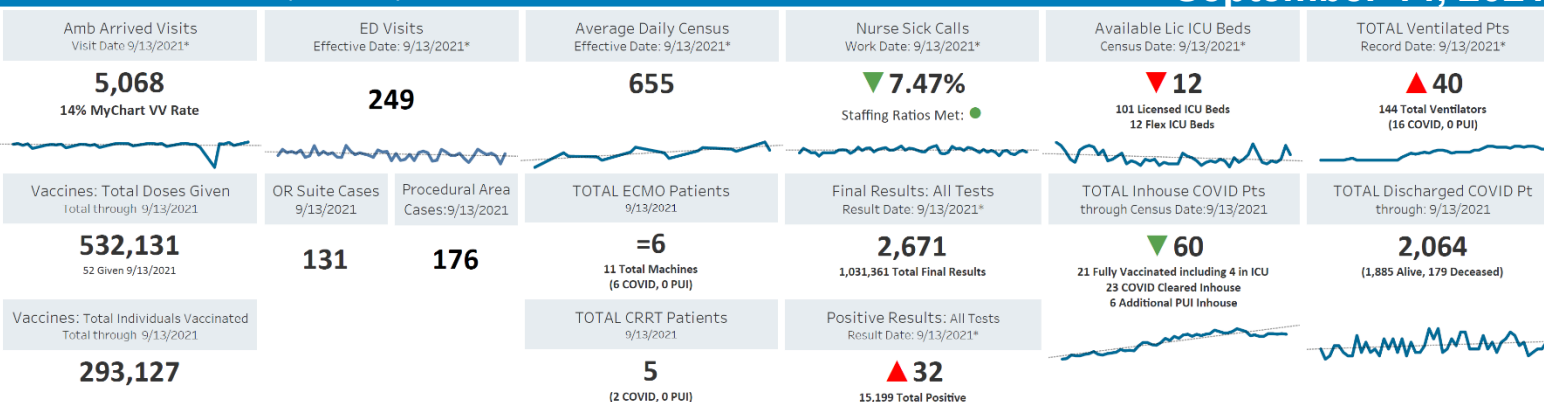
COVID Admits 60
COVID Ventilators 16

UCSD Health Tableau October 12, 2021

9

Daily Inhouse COVID Patients by Ventilator Status
Ventilated patients counted if on vent at any time of the day

Patient on Ventilator?
No
Yes

UCSD Health Tableau October 12, 2021

10
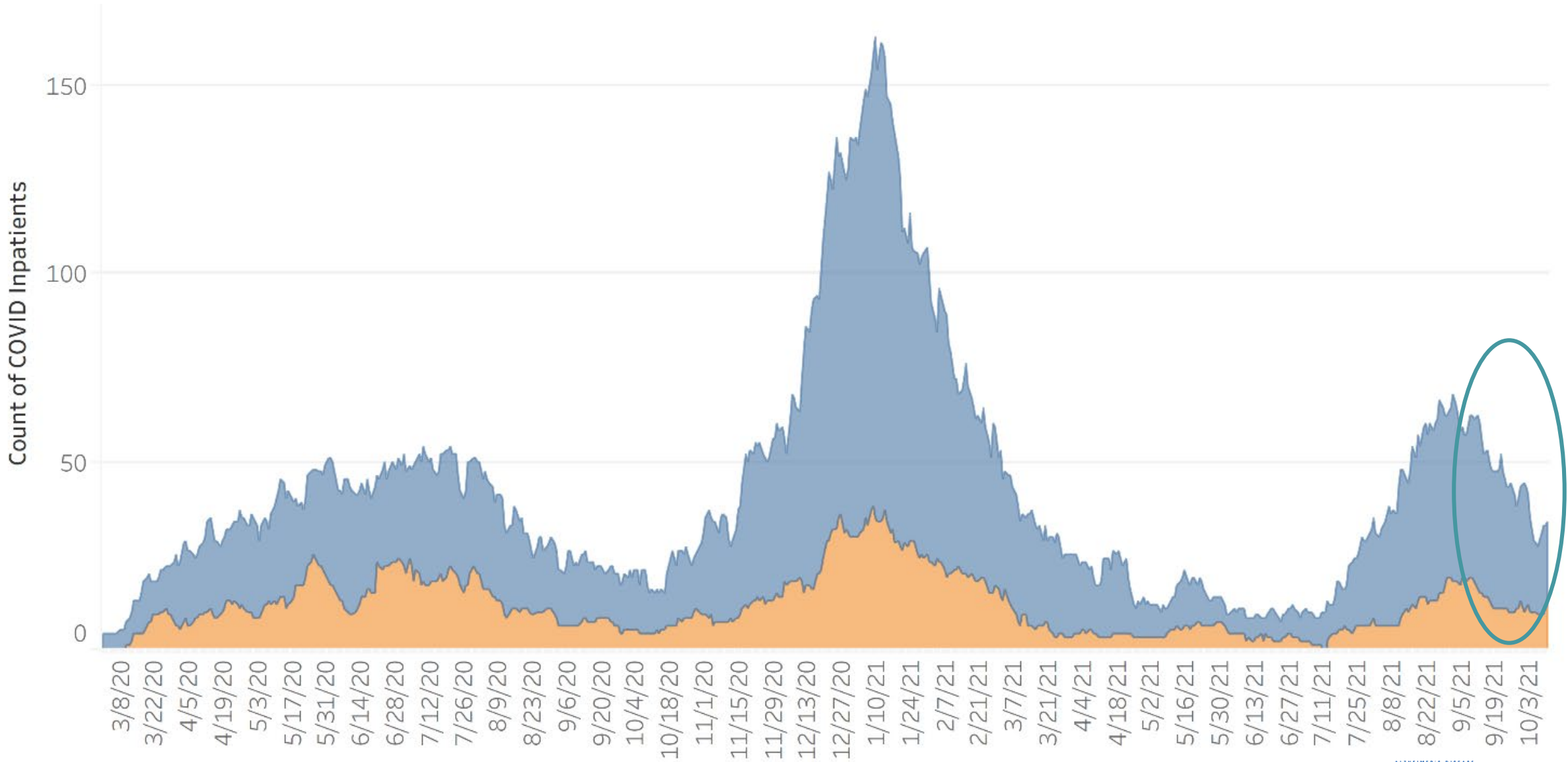
Positive COVID Tests UCSD Health by Vaccination Status

UCSD Health Tableau October 12, 2021

11
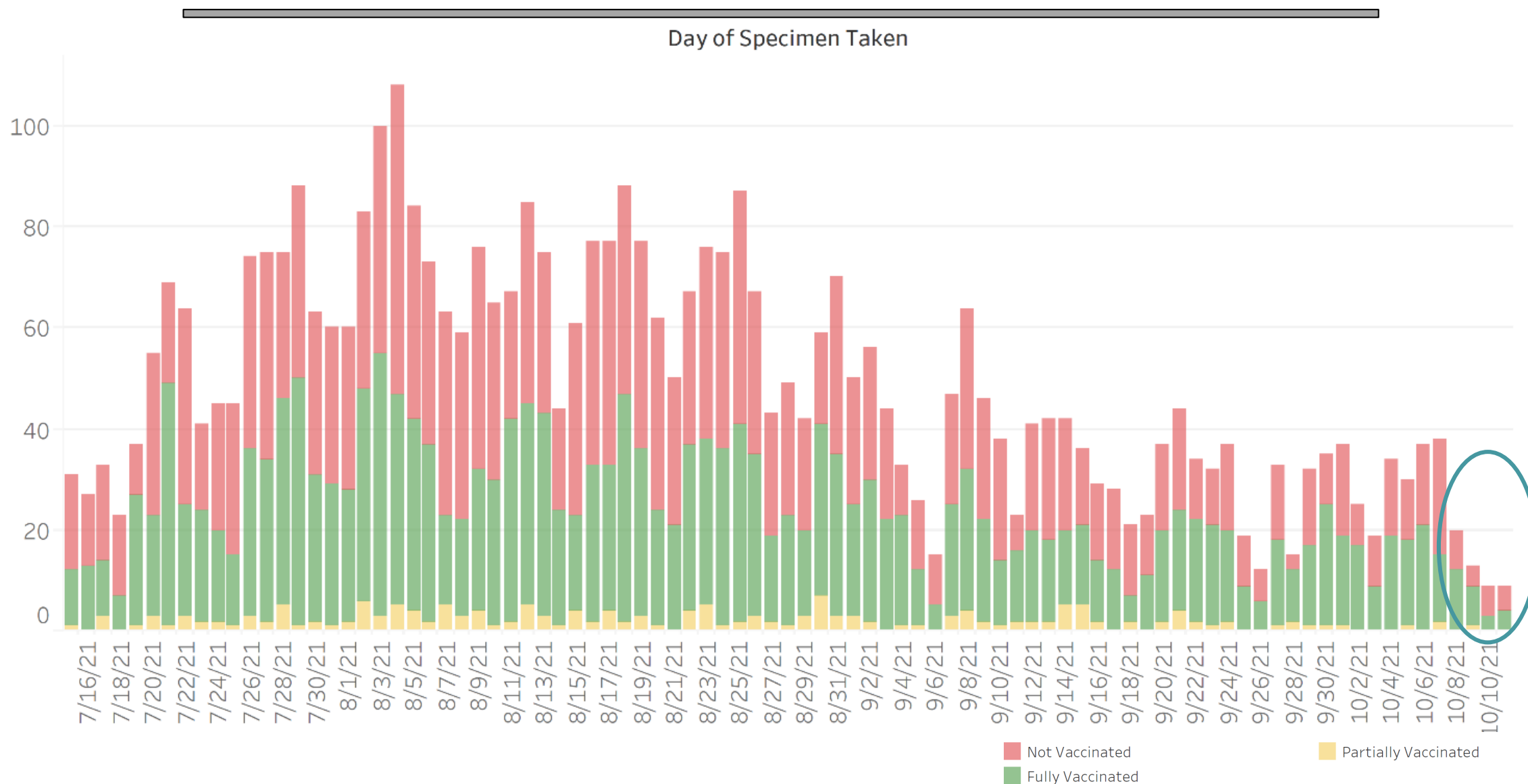
UCSD All Tests Final Results

UCSD Health Tableau October 12, 2021

Legend:
- Negative Results
- Positive Results
- 7 Day Rolling Avg % Positive

12
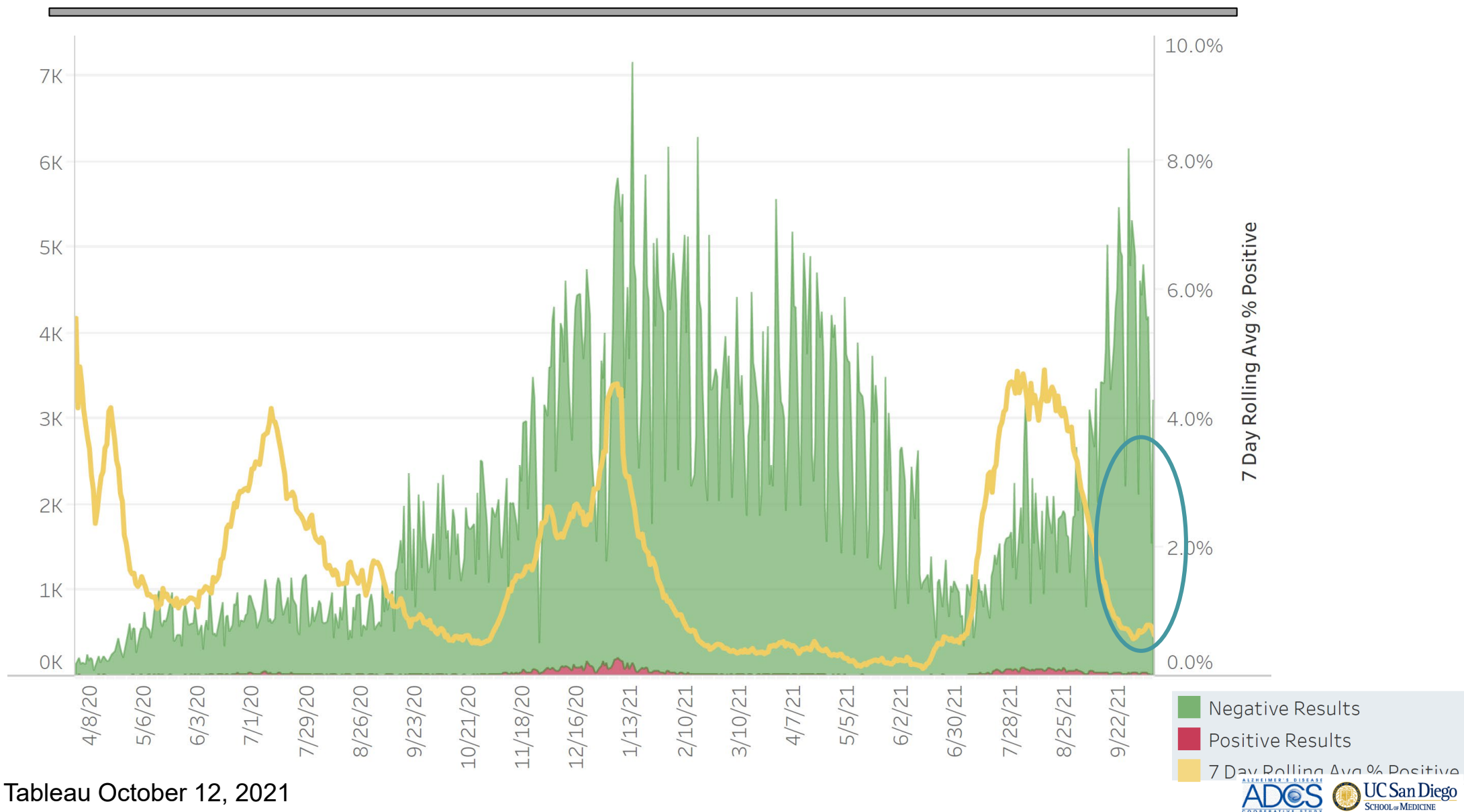
COVID-19 Vaccines: Booster Shots

■ FDA advisory panel meets later this week to consider extra doses of Moderna and J&J vaccines

■ Regulators recently authorized booster shots of Pfizer

 ■ including elderly, adults with underlying conditions, those who work/live in high-risk settings, eg health, grocery workers

■ FDA could make decision within days, then handing off to CDC for its own decision. CDC's next vaccine advisory meeting is Oct. 20-21

  ■ Last month, Moderna said third shot at half dosage was safe and produced stronger immune response than seen after second dose

  ■ J&J said second dose of its single-shot vaccine was safe and boosted protection against symptomatic infection from around 70% to 94% when administered two months after first dose

  ■ FDA could authorize Moderna and J&J boosters under same criteria as Pfizer or broaden number of Americans eligible to receive extra shots

■ County of SD for now recommends these groups receive third dose:

  ■ People 65 and older; ages 18> in long-term care settings; people 50–64 years old with underlying medical conditions

■ CDC chief Dr. R Walensky: Getting booster is "walk, don't run" situation

Source: CNBC/SD County News Center

COVID-19: Flu Shots
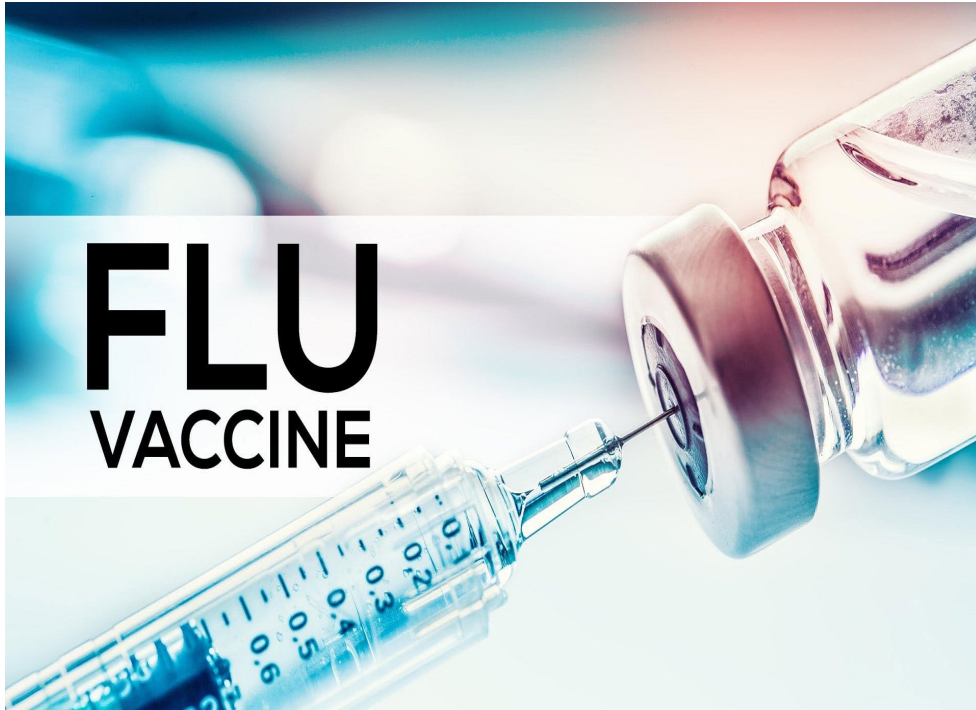
Sources: Washington Post/UCSD Blink

- Health officials urging Americans to get flu shots,
    - warning flu season that didn't materialize when society was shut down last year
    - could come roaring back and strain hospitals in months ahead
- Experts say Americans have built up less natural immunity against influenza because so few were infected in 2020
    - Masks, physical distancing, staying home among reasons cited for low flu numbers in 2020
    - Pattern seen in spring/summer 2021 resurgence of common viruses including respiratory syncytial virus (RSV).
        - Hospitals reported high numbers of toddlers with severe cases, as they were not exposed as infants in 2020
        - Hospitals concerned that COVID and RSV would stretch O2 supply and staffing if flu and coronavirus admissions surged together
        - Flu viruses may roar back in reopened schools, workplaces and businesses, especially where masks are not mandated
- Hospital leaders fear burnout among doctors, nurses, respiratory therapists who have been on front lines of the pandemic
    - Officials hopeful public has learned good infectious-disease practices after 18 months of pandemic life
- UC San Diego Health: Flu immunizations available for patients, staff, including high-dose vaccine recommended for people over 65.
    - Options include drive-thru, physician clinic, pharmacies, UCSD Express Care sites

Data Management Presentation

Data Management Team

Data Management

Jen Mason, Sean Kipperman, Kevin Zielin and Lorena Naylor for the ADCS Data Management Team
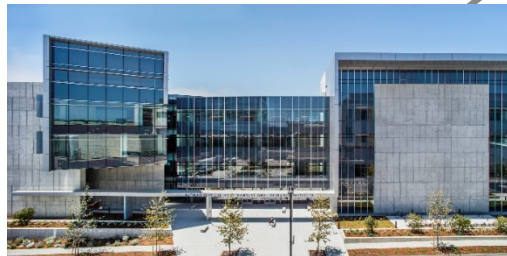
Agenda

Data Management Team Jen

ADCS Initiatives Jen

Where we've been and where we are Jen

TrialMaster EDC Key Feature Sean

Clinical Conductor CTMS Key Features Lorena

Ad-hoc Reporting Key Features Kevin

Jen Mason

Dir, Data Management

Sean Kipperman

Clinical Data Manager

Kevin Zielin

Sr. Programmer Analyst (Python)

Tho Nguyen

Data Analyst

Li Cui

Data Analyst

Lorena Naylor

CTMS Analyst

Leela Vemulapalli

Contract Data Manager

DM team

Susan Castellino

Contract Data Manager

ADCS Initiatives

Focus on the Data

- AXIOM
- Ad-hoc Reporting
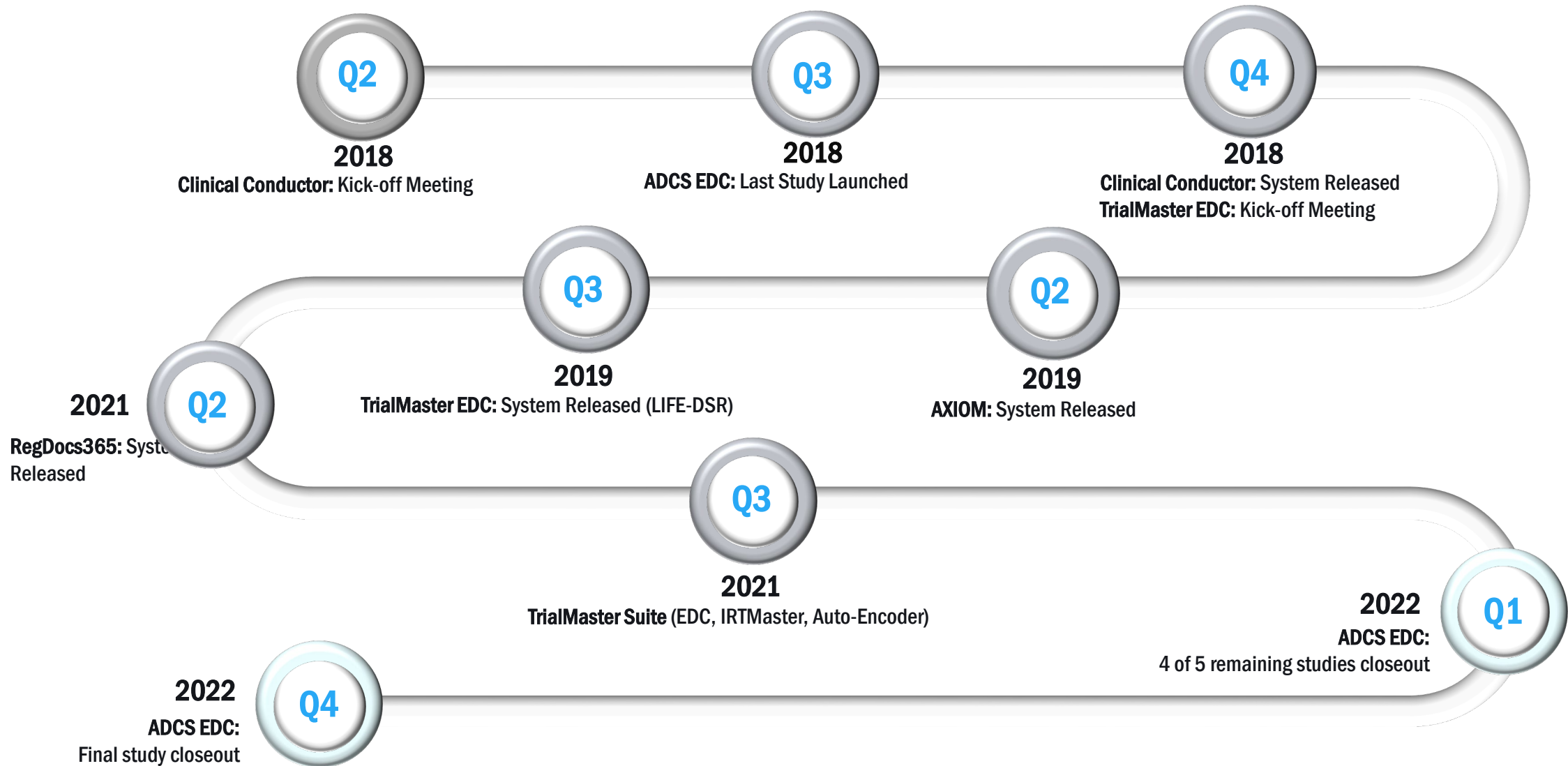
Data Standards

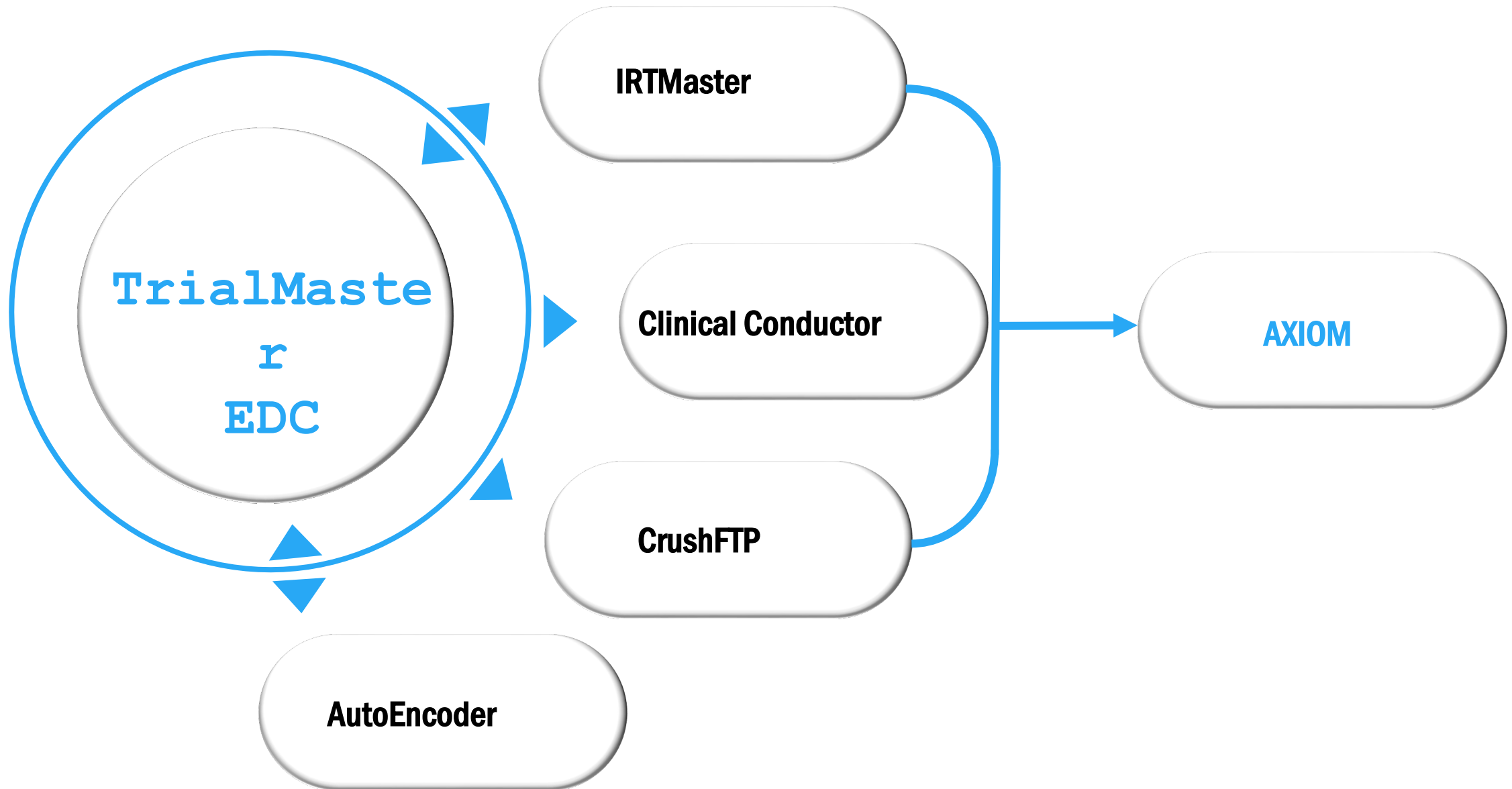- "ADCS Gold Standard" to CDISC

EDC and CTMS (SaaS)
Software-as-a-Service

- Sunset ADCS EDC and CTMS
- Roll-out TrialMaster EDC and Clinical Conductor

Where we've been

Q2

2018
Clinical Conductor: Kick-off Meeting

Q3

2018
ADCS EDC: Last Study Launched

Q4

2018
Clinical Conductor: System Released
TrialMaster EDC: Kick-off Meeting

Q3

2019
TrialMaster EDC: System Released (LIFE-DSR)

Q2

2019
AXIOM: System Released

Q2

2021
RegDocs365: Syste Released

Q3

2021
TrialMaster Suite (EDC, IRTMaster, Auto-Encoder)

Q1

2022
ADCS EDC:
4 of 5 remaining studies closeout

Q4

2022
ADCS EDC:
Final study closeout

Where we are now

TrialMaster EDC: Key features

Dynamic Monitoring
Allows automated selection of forms for source data verification (SDV), based on site risk ratings and actual collected data, such as if a participant experiences a Serious Adverse Event.

TrialMaster EDC: Key features
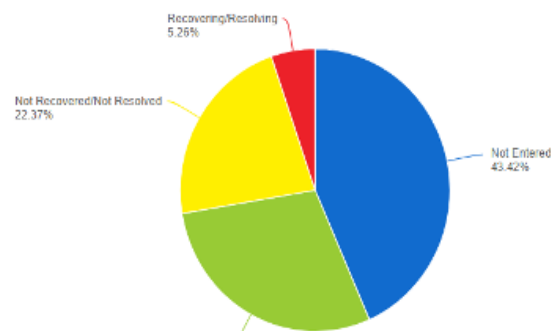
Report Wizard with Dashboard

Provides data management with a report builder wizard to create custom listings, charts and graphs that may be displayed through a dashboard on the EDC homepage.

Adverse Event Summary

Page 1 of 6

Patient ID	SDV Level	Adverse Event	Start Date	Ongoing	End Date	Duration (Days)	Severity	Relatedness	Outcome	Serious?	Age	Sex
001-001_XY	All forms	Asthma	2018/06/12	No	2018/06/14	3	Moderate	Not Related	Recovered/Resolved	Yes	54	Female
001-001_XY	All forms	Phenylalanine screen	2018/06/15	No	2018/06/15	1	Mild	Not Related	Recovered/Resolved	No	54	Female
001-001_XY	All forms	Drug-induced hepatoxicity	2018/06/08			17				No	54	Female
001-001_XY	All forms	Hemodialysed	2018/06/08			17				No	54	Female
001-001_XY	All forms	Apoplastic thyroid cancer	2018/06/08			17				No	54	Female
001-002_JK	All forms	Tachycardia	2018/06/14	No	2018/06/14	1	Severe	Possibly Related	Recovered/Resolved	Yes	53	Male
001-002_JK	All forms	Asthma	2018/06/14	No	2018/06/18	5	Mild	Not Related	Not Recovered/Not Resolved	Yes	53	Male
001-002_JK	All forms	MI	2018/07/30	Yes		26	Moderate	Not Related	Not Recovered/Not Resolved	Yes	53	Male
001-003_PW	All forms	Headache	2018/06/19	No	2018/06/25	7	Moderate	Not Related	Not Recovered/Not Resolved	Yes	53	Male
001-003_PW	All forms	asthma	2018/06/18	No	2018/06/25	8	Mild	Not Related	Not Recovered/Not Resolved	No	53	Male
001-003_PW	All forms	tachycardias	2018/06/18	No	2018/06/18	1	Severe	Possibly Related	Recovered/Resolved	Yes	53	Male
001-004_YU	All forms	Tachycardia	2018/06/20	No	2018/06/20	1	Moderate	Not Related	Recovered/Resolved	Yes	63	Female
001-004_YU	All forms	MI	2018/06/20	No	2018/06/20	1	Moderate	Not Related	Recovered/Resolved	Yes	63	Female
001-005_MR	All forms	Headache	2018/06/20	No	2018/06/20	1	Mild	Not Related	Recovered/Resolved	No	63	Male
001-005_MR	All forms	Tachycardia	2018/06/20	No	2018/06/20	1	Severe	Not Related	Not Recovered/Not Resolved	Yes	63	Male

Outcome

Recovering/Resolving 5.26%
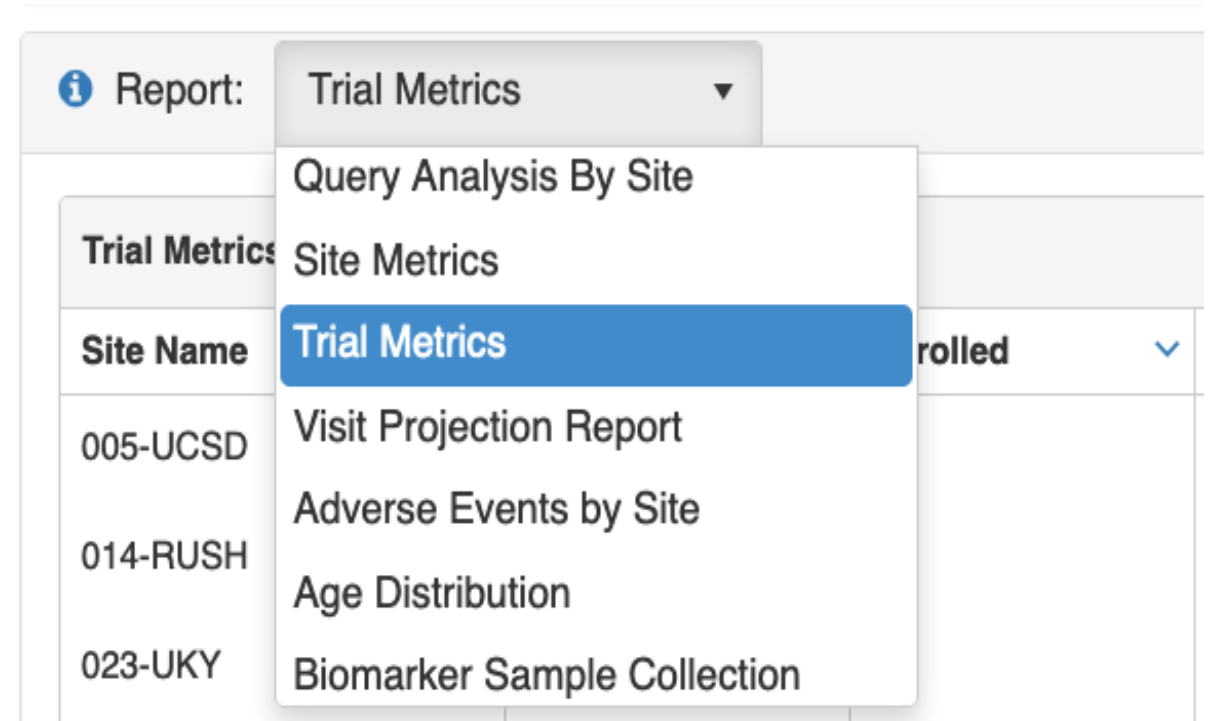
Not Recovered/Not Resolved 22.37%

Not Entered 43.42%

TrialMaster EDC: Key features

Report Wizard with Dashboard

- Users with report permissions may view and download reports in word, excel or pdf.

- Aggregate data reports may be scheduled and subscribed to. Subscribed users will receive an email with the report as an attachment.

TrialMaster EDC: Key features

AutoEncoder (AEC)

Provides medical safety the ability to code with MedDRA and WHODrug dictionaries
with options for auto-coding, manual coding and customizable review and approval workflows.

- Dashboard on the homepage displays a summary of coding across studies
- Transmission of verbatim term from EDC to AEC and coding back to EDC once approved
- Detail coding reports available to drill-down on specifics

AutoEncoder Dashboard

Select a module:

↑Trial	Module	Dictionary	Code	Approve	Organization	Acti...	Job Status
LIFE-DSR	📰 WHODRG	WhoDrug C3 Global C3 Global 2019Q1	416	0	UCSD-ADCS	Reports	100% Completed
VIVA-MIND	📰 AECODE	MedDRA MedDRA 24.0	0	0	UCSD-ADCS	Reports	
VIVA-MIND	📰 WHODRG	WhoDrug C3 Global C3 Global 2021Q1	0	0	UCSD-ADCS	Reports	

Clinical Conductor: Key features

Integration with TrialMaster EDC to Support Quarterly Site Payments

- Enrollments and CRF completions are pushed from TrialMaster EDC to Clinical Conductor.
- Allows the "Click and Create" of site payment invoices by selecting visits and add-ons.
- Study sites may view their payment details through their own site portal.

Clinical Conductor: Key features
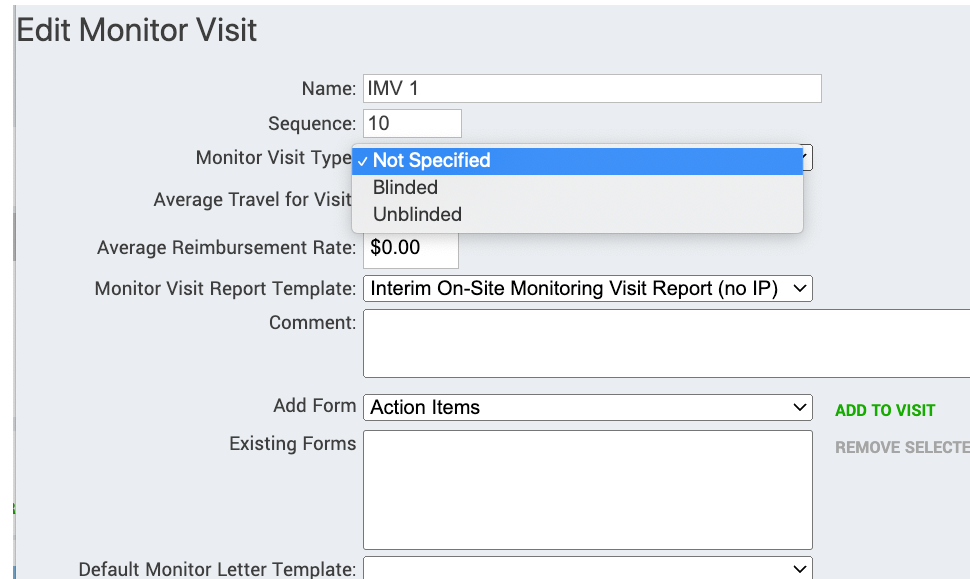
Monitoring Module

Visit Report and Letter Templates
- No programming required for set-up.
- Status tracking; unresolved action items will be carried through to next visit.

Standard Visit Plan
- Configure visits based on study-specific monitoring plan.

Clinical Conductor: Key features

Custom Built Reports

Define customized reports programmed by the vendor and accessible via the custom report list.

CCID	Report
4	Monitor Engagement Tracking
2	Monitor Tracking
1	Site Payment Details
6	Site Payment Summary
3	Staff Details

Clinical Conductor: Need Assistance?

- adcsit-helpdesk@ucsd.edu

- Document Share > training materials

Ad-hoc Reporting: `Overview`

Provide data managers and study team with programming support for data exploration, cleaning and analysis across the ADCS study portfolio

Framework consists of:

- **Issue Tracking:** GitHub

- **Programming:** Python (primarily) and SQL

- **Source Data:** Pydraughts (access data warehouses via HTTP request)

- **Publish Output:** Jupyterhub Notebook

New feature releases:

- Addition of data visualizations

- Delta reports (carry over of DM review comments and query status)

- Enhanced discrepancy flagging

Ad-hoc Reporting: Workflow
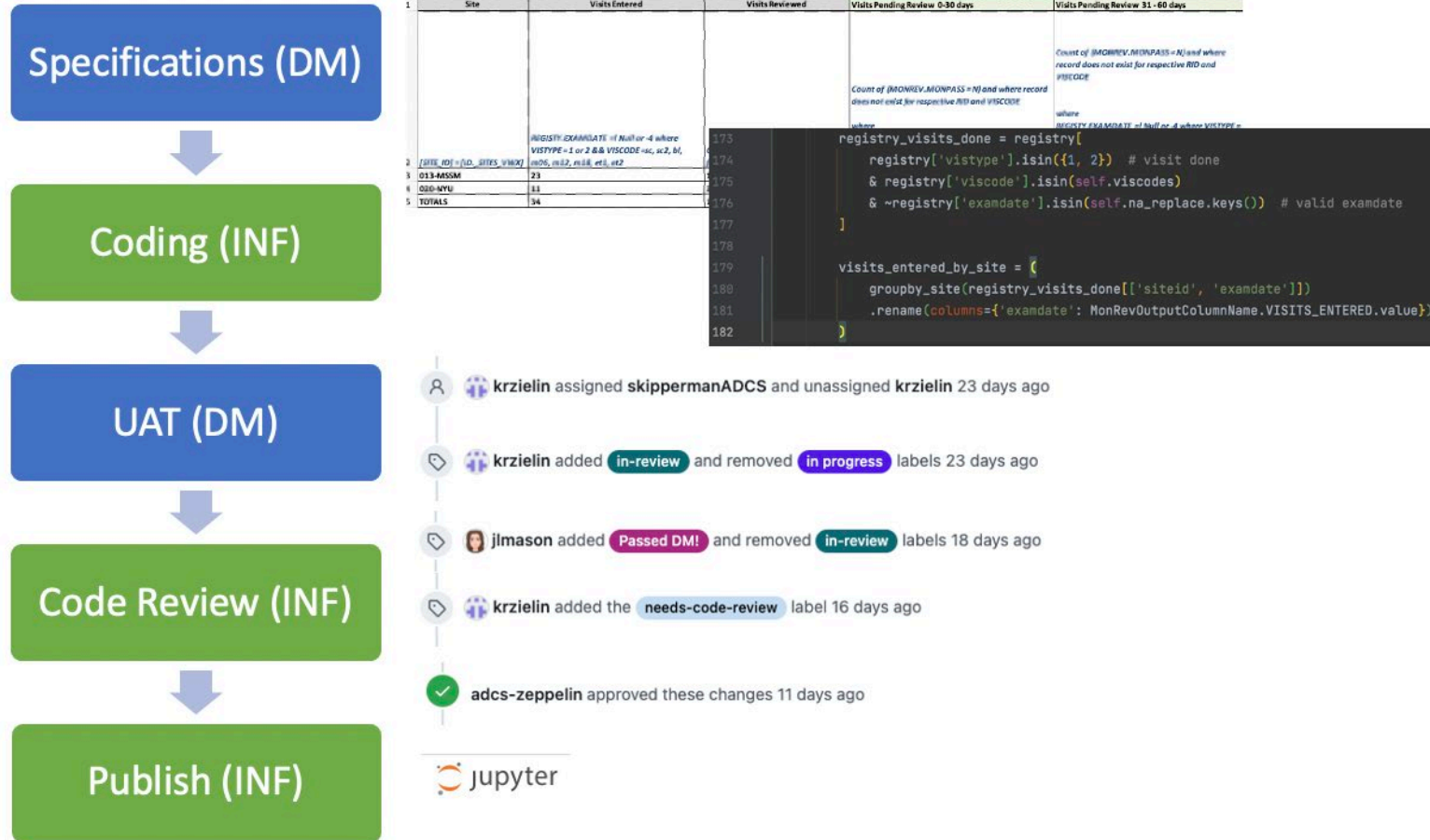
Ad-hoc Reporting: Example Visualization

ADAS Word Recall Score Distribution for Randomized Participants

viscode	count	mean	std	min	25%	median	75%	max
bl	296	3.68	1.59	0	3	4	5	9
m06	238	3.59	1.63	0	2	3	5	8
m12	208	3.61	1.73	0	2	4	5	8
m18	151	3.78	1.85	0	2	4	5	10
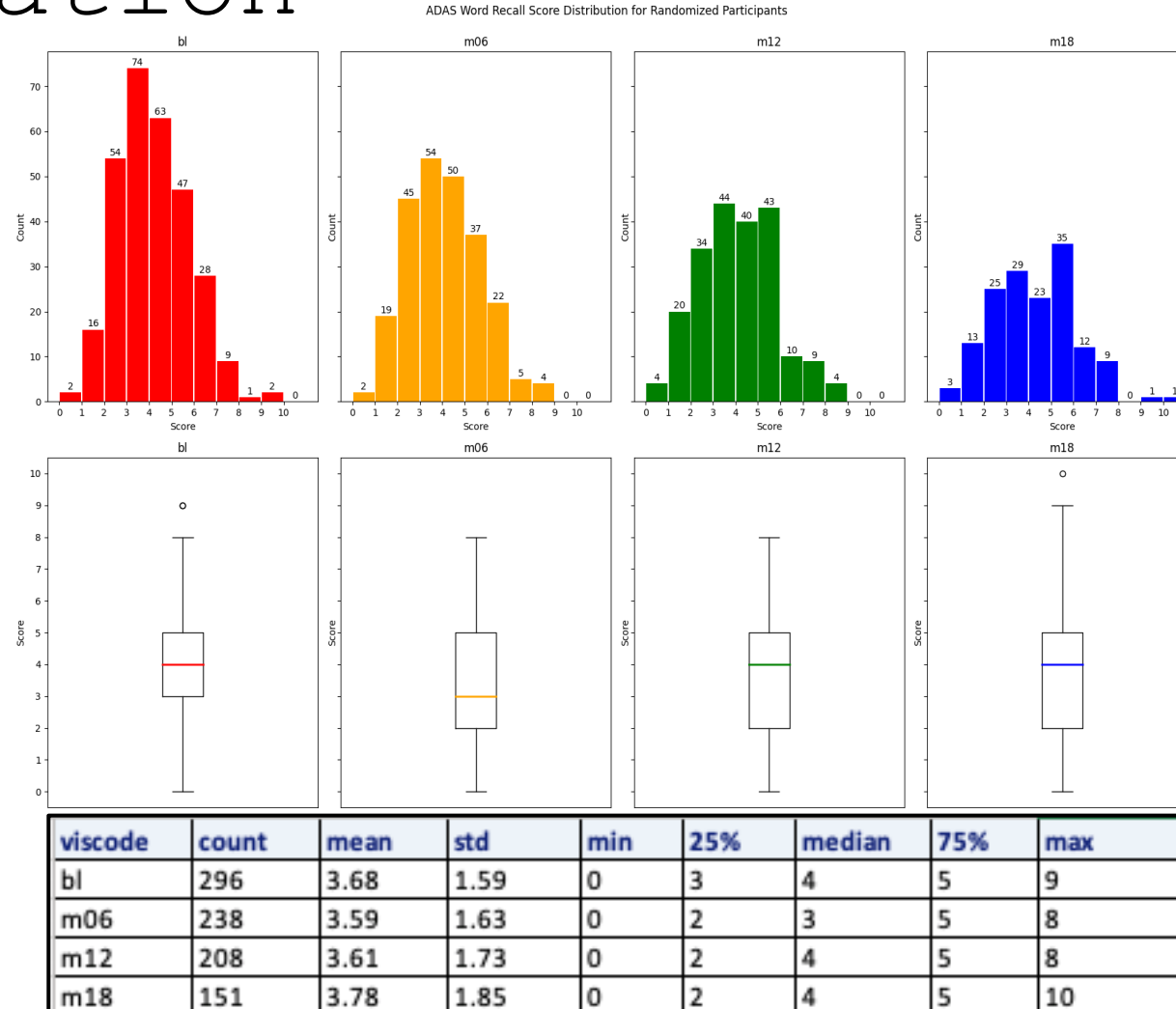
Ad-hoc Reporting: Example Delta Report

- Carry over of DM comments and query status each time the report is run
- Allows DM to focus the data review on new and/or changed data

M	N	O	P	Q	R	S	T	U	V	W
M18: Accession Number	M18: Results Received	ET1: Collection Date	ET1: Accession Number	ET1: Results Received	ET2: Collection Date	ET2: Accession Number	ET2: Results Received	DM Comments	QID	QStatus
6222364	Y									
6311107	Y							20210820 SK: Query issued to site to confirm Accesssion # based on URMC record	15492	R
6311663	Y							not have supplies on site, please assign Kid ID" - Requisition request sent to URMC; 20210820 SK: Query issued to site to confirm	15493	R
								Query issued - QID 15409	15409	C
6311133	Y									

Ad-hoc Reporting: Example Enhanced Flagging

- Displays data discrepancies within the last column
- Highlights respective cells for a quick visual queue

Registry	Urine Collection	Blood Collection	Adverse Events	Participant Demographics	ECG	Drug Accountability	Rescue Lorazepam Use	Vital Signs	Study Drug Exposure	Fall Risk Assessment	Deviation Log	Visit Schedule	For Review: Date Columns
08/09/2021	N/A	11/23/2020	07/26/2021	05/04/2021	05/04/2021	08/09/2021		08/09/2021	08/09/2021	05/04/2021	05/04/2021	08/10/2021	
09/02/2021	N/A	06/15/2021	N/A	06/15/2021	06/15/2021	09/01/2021	N/A	09/02/2021	09/02/2021	06/15/2021	08/29/2021	09/16/2021	
10/07/2021	12/03/2020	05/17/2021	10/07/2021	09/21/2021	12/03/2020			10/07/2021		09/21/2021	N/A	09/30/2021	
10/04/2021	09/24/2021	09/24/2021	N/A	09/24/2021	09/24/2021	10/04/2021		10/04/2021		09/24/2021	N/A	09/30/2021	
01/28/2020	02/04/2020	N/A		01/28/2020	01/29/2020			02/09/2020		01/28/2020		N/A	
10/01/2021	10/03/2021	03/10/2021		10/01/2021	10/01/2021			10/01/2021		10/01/2021		10/08/2021	
07/12/2021	03/12/2021	04/28/2021	06/29/2021	05/04/2021	04/28/2021	07/02/2021		07/12/2021	06/25/2021	05/04/2021	05/14/2021	07/09/2021	Registry, Vital Signs, Visit Schedule
10/26/2018	10/30/2018	10/29/2018	11/02/2018	10/26/2018	10/29/2018			10/26/2018				N/A	
04/22/2019	02/01/2019	02/01/2019	02/26/2019	01/31/2019	02/06/2019	05/16/2019	03/23/2019	05/15/2019	05/15/2019	01/31/2019		05/07/2019	

Thank you for your attention.

Questions?

Administrative Updates

Carol Evans

Coming Soon…Benefits Open Enrollment

Open Enrollment

OCTOBER 28 – NOVEMBER 19, 2021

UC San Diego   UC San Diego Health

During Open Enrollment…

You may add, change or drop:
- Healthcare plans
- Qualified dependents
- ARAG Legal
- Supplemental health plans
- Flexible Spending Accounts (FSAs)
  - Note: you must enroll in your FSA each year during Open Enrollment

You may not make changes to:
- Voluntary disability insurance
- Life insurance

- **Open enrollment** starts **Thursday, Oct. 28**, at 8 a.m. ends **Friday, Nov. 19**, at 5 p.m.
  - Change from usual deadline of Tuesday before Thanksgiving
  - Still 3+ weeks to make choices

- **Virtual Benefits Fair**
  - Available 24/7 **until November 24**
  - Explore virtual booths with resources, videos, and representatives available to answer questions

- **Webinars and Office Hours**

https://ucnet.universityofcalifornia.edu/news/2021/09/open-enrollment-sneak-peek-a-new-deadline-and-change-of-pharmacy-benefit-managers-for-uc-ppo-plans.html

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ADCS Workplace Model Plan

- ADCS "Workplace Model Plan" **Approved on September 27, 2021**
  - Based on business needs and Directors/Managers discussions with direct reports
  - Covers **ADCS only**

- 30 days' notice sent on September 22, 2021, effective date: **October 25**
  - Can return earlier

- Staff designated as hybrid, please contact Core Director and Carol Evans to coordinate being onsite starting **Oct 25**

- Contact your Core Director or Carol Evans with any questions

Alzheimer's San Diego Walk

- Thank you to everyone who attended the 2021 Walk to End Alzheimer's!

- This week: **Alzheimer's San Diego** Walk
    - Saturday, October 16th at Balboa Park – 8:00 AM
    - Organizer/Team Captain: Jennifer Reichstadt
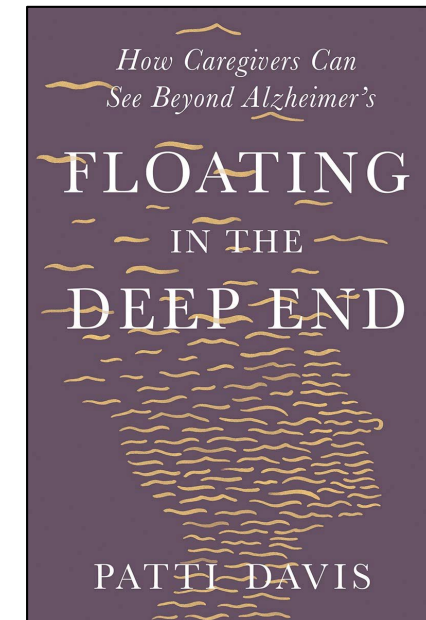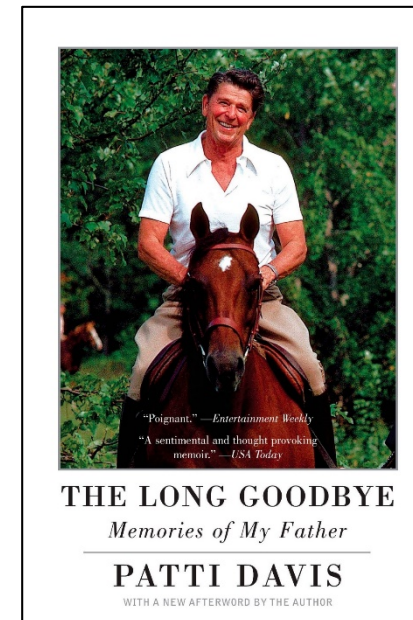   - Register & come to UCSD table for a free T-shirt: https://tinyurl.com/2021UCSDwalk

ADCS Town Hall
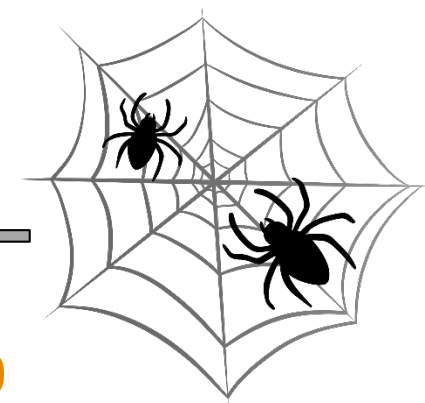## *Special Guest Speaker!*

Save the date: October 27

Patti Davis

Author, daughter of former President Ronald Reagan

ADCS Social Committee Halloween Event

Please join the ADCS Social Committee on Friday, October 29 at 4:30PM Pacific!

- **Some suggestions include:**
  - A Spo0oky ZOOM background 👻
  - Dress up in your Halloween costume best and we can vote on our favorites!
  - Share in real-time or a photo of pumpkins you (and your family) carved 🎃
  - If you don't feel like dressing up or carving a pumpkin, you can share a Halloween photo of you/your kids/family/pets

Comments/Questions