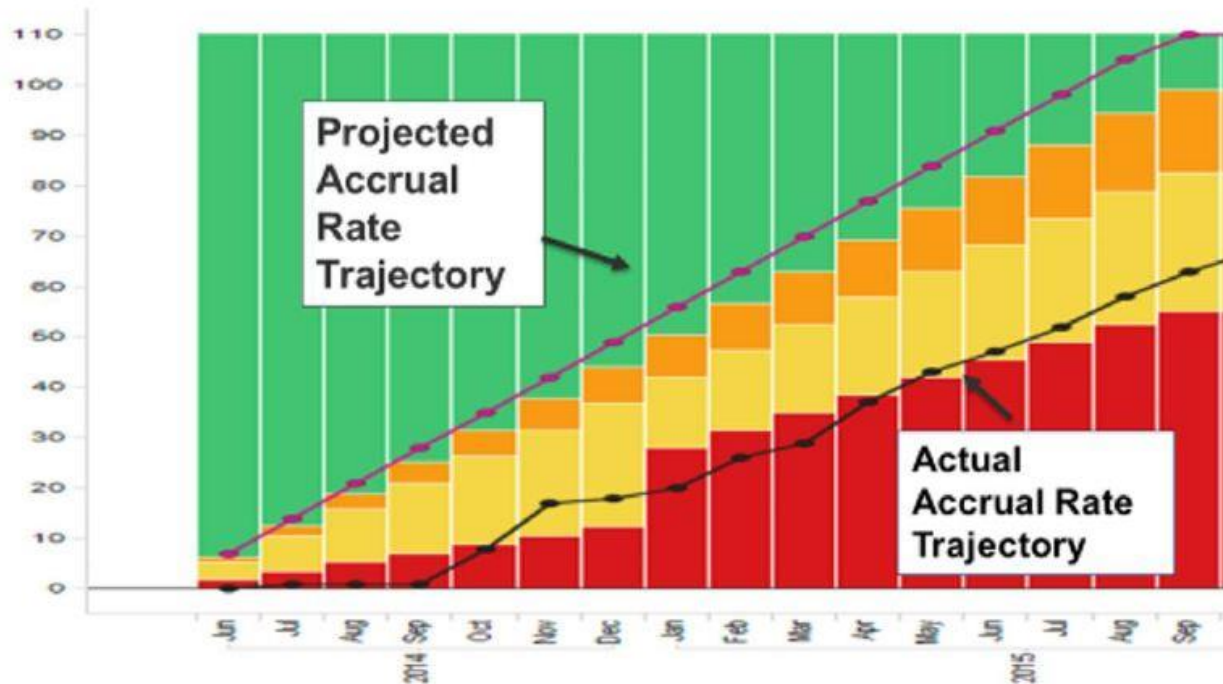


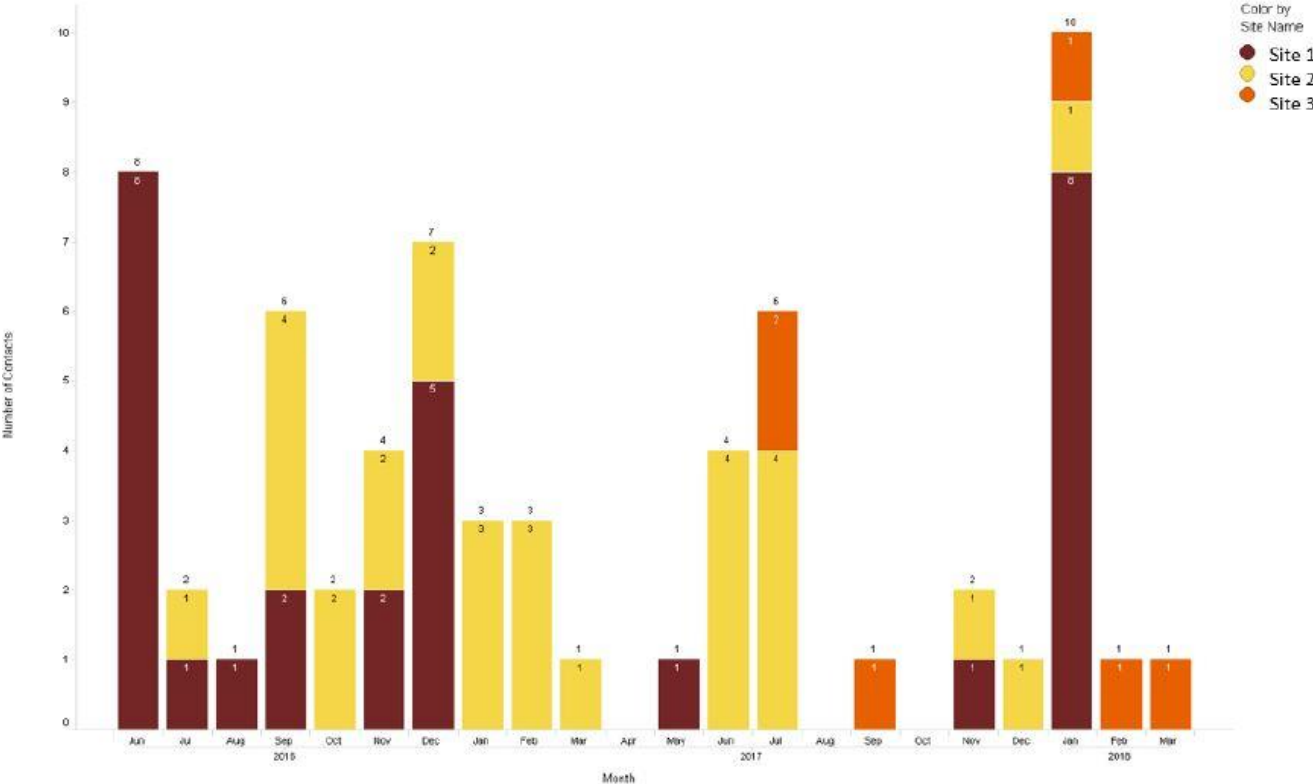
Example of an Accrual Quality Improvement and Tracking Program (AQuIP) Report

AQuIP Zone Monitoring Report



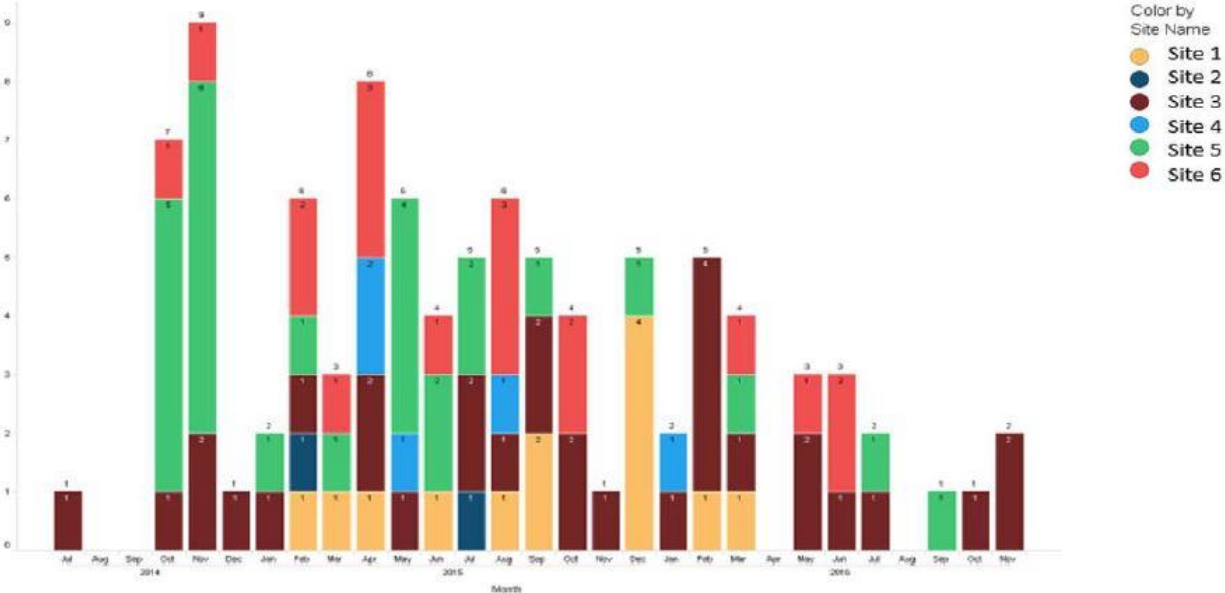
This report provides a visualization of accrual progress based on a comparison of the actual current accrual rate with accrual rate benchmarks or milestones, presented on a background of color-coded accrual performance zones.

Participants Contacted Per Site Per Month



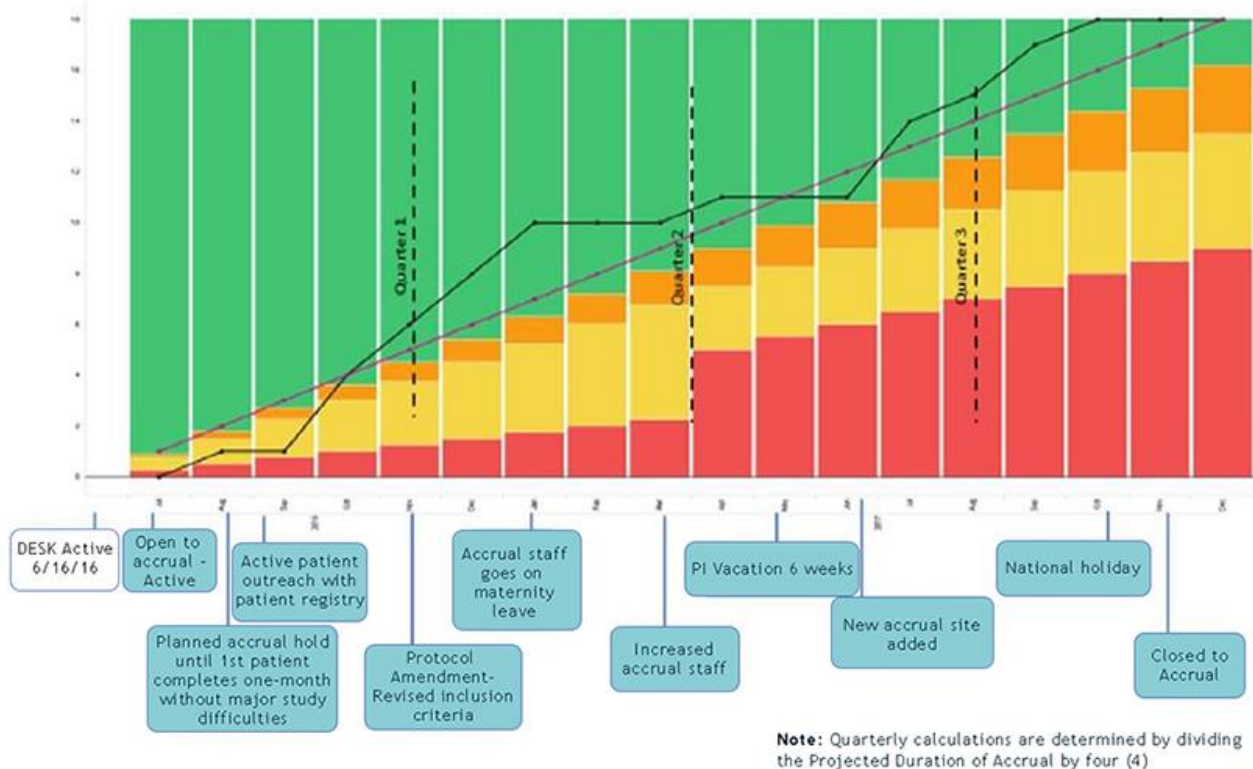
This bar graph illustrates the number of participants contacted by each accrual site each month.

Participants Starting Intervention Per Site Per Month



This bar graph illustrates the number of participants who started the study intervention for each accrual site each month.

Annotated Accrual Timeline: Every Study Has a Story



This report provides information about a variety of events, situations, changes or conditions that may influence overall study accrual as opposed to strategies or factors that affect accrual of individual participants or potential participants. The events are superimposed onto the Accrual Zone Monitoring Report timeline to illustrate any temporal or possibly causative correlation between events and the overall study accrual rate.

As an example, this graph shows changes in the slope of the “actual” accrual rate trajectory that correspond to some of the following events:

- opening of accrual sites
- planned accrual hold
- active outreach using patient registry
- protocol amendment that modifies eligibility criteria
- accrual staff on maternity leave
- extended PI vacation
- national holiday
- accrual closure

AQuIP Accrual Report

This Excel workbook provides the data collected through the AQuIP Online Accrual Report System.

	A	B
1	Attribute	Value
2	Protocol Title	
3	Targeted Enrollment	
4	Projected Accrual Per Month	
5	Projected Completion Date	
6		
7		
8		
9		
10		

The Protocol Information worksheet includes: Protocol Title, Targeted Enrollment, Projected Accrual Per Month, and Projected Completion Date.

Accrual Report – Entry

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
1	Protocol Number	Site Name	Participant Id	First Contact Date	Consent Date	Intervention Start Date	Recruitment Strategies	Reason Consent Not Signed	Specification Text	Consent Not Signed	Not On Study Intervention	comments	contact	consent	intervention
2															
3															
4															
5															
6															
7															
8															
9															
10															

The fields gathered for the Accrual Report worksheet include: Protocol Number, Site Name, Participant ID, First Contact Date, Consent Date, Intervention Start Date, Recruitment Strategies, Reason Consent Not Signed, Specification Text, Consent Not Signed, Not on Study Intervention, comments, contact, consent, and intervention.

Accrual Report – Totals

	A	B	C	D	E	F	G	H
1	Site Name	Contacted	Pending Consent for Screening	Not Consented for Screening*	Consented for Screening	Pending Start of Study Intervention	Study Intervention NOT Started**	Started Study Intervention
2								
3								
4								
5	* Will not start consent process or decided to not sign consent							
6	** Did not meet I/E criteria or dropped/were terminated before study intervention started							
7								
8								
9								
10								

The fields obtained for the Accrual Report Totals worksheet include: Site Name, Contacted, Pending Consent for Screening, Not Consented for Screening (will not start consent process or decided to not

sign consent), Pending Start of Study Intervention, Study Intervention NOT Started (did not meet I/E criteria or dropped/were terminated before study intervention started), and Started Study Intervention.

Recruitment Journal

	A	B	C	D	E	F	G	H
1	Site Name	Contacted	Pending Consent for Screening	Not Consented for Screening*	Consented for Screening	Pending Start of Study Intervention	Study Intervention NOT Started**	Started Study Intervention
2								
3								
4								
5	* Will not start consent process or decided to not sign consent							
6	** Did not meet I/E criteria or dropped/were terminated before study intervention started							
7								
8								
9								
10								

The data collected for Recruitment Journal worksheet include: Site Name, Contacted, Pending Consented for Screening, Not Consented for Screening (will not start consent process or decided not to sign consent), Pending Start of Study Intervention, Study Intervention NOT Started (did not meet I/E criteria or dropped/were terminated before study intervention started), and Started Study Intervention.