UCSF Helen Diller Family Comprehensive Cancer Center

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Background

Regulatory audits and inspections can happen at any time and the onus is on the study team to always be 'audit ready'. While addressing findings in monitoring reports is an important step in the audit preparation process, deficiencies and subsequent responses are seldom shared outside the study team and rarely inspire organizational quality improvement initiatives. The Helen Diller Family Comprehensive Cancer Center (HDFCCC) at the University of California San Francisco (UCSF) developed and implemented an internal peer-to-peer chart review process aimed at improving data accuracy, and building a culture of quality improvement and high standards.

Methods

A comprehensive checklist (Figure 3) was developed by a working group with representation from each clinical research program at the HDFCCC. Each month, clinical research staff in each program review study charts with a focus on:

- Charts completed by new staff;
- New studies; and,
- Random selection of active patients.

All CRCs have at least one chart reviewed per year.

The results of peer-to-peer chart reviews are reviewed in two phases:

- Monthly within each HDFCCC clinical research program. Programmatic reviews identify individual training gaps and areas for process improvement in program specific workflows.
- Quarterly HDFCCC wide reviews. Center wide reviews identify common oversights and omissions across the organization, and areas for overall process and training improvement.

The two step review of findings ensures communication and immediate action first within the program, then organizational training and workflow gaps are discussed in groups with representation across the entire HDFCCC.

Outcome

In the first 12 months of implementation, 182 charts were reviewed (21% of all therapeutic accruals) using the comprehensive checklist. The number of findings per chart decreased from 2.6 to 2.1 over the year. Sponsors have an ecdotally commented that study charts are cleaner, and staff doing the chart reviews have developed a better understanding of processes, workflows and the need for clear and concise documentation.

Policy review is a key component of the review process, and while policies have been updated over time, older trials were following older policy versions when they first started. The version of the policy at the time of procedure execution, and the implication of changes in the revised policy, need to be considered in the review process.

Clinical research staff buy-in into the process and its objectives was fundamental in the success of the initiative.

Delaved PI Review

Eligibility Source Documents

Eligibility Signatures

Labs Not Graded

Missing Source Documents (non-eligibility)

Documentation Practices

Consent Process not Documented **Off Treatment Form** Missing

Missing Protocol Procedure

Re-consent Delays

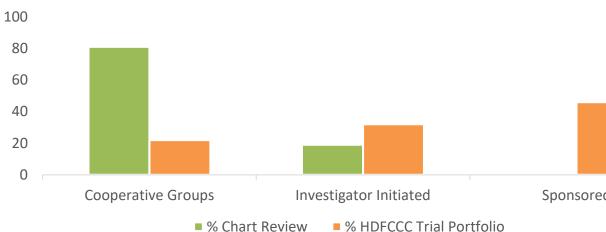
Figure 1: Top 10 Observations by Category Primary observations found in first year of chart review implementation. The most common findings were documentation

Peer-to-Peer Quality Chart Review

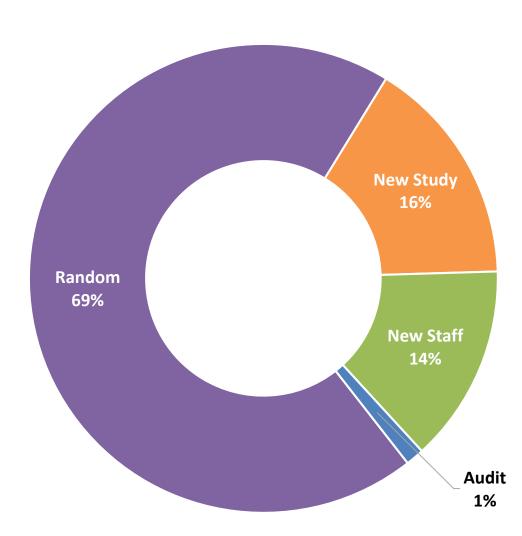
Future Directions

As the initiative moves into the second year efforts are underway to:

Examine the trial portfolio in each progr tailor the chart review priorities based of external oversight already in place.



- Establish a system for a cross-program of charts to ensure high standards are consistent across all programs.
- Formalize the quarterly review of finding update policies, guidelines and training on findings.



of eligibility and timeliness of investigator review.

Figure 2: Reason for Chart Review

Most charts were selected at random and unexpected, 1% were selected as part of sponsor audit preparations.



	Comprehensiv Cancer Center	/e	I Chart R	eview Che	cklist				
	Study Name:			PI:		Pt ID:		al	
	Reviewer: Item		Yes	Review Dates	: Comments	CC#:			
nd			(Done/ Available)	(Provide comment)					
	Review: -protocol								
	-study calendar								
	-study procedures -reporting requirements for adverse events								
	Screening/Consent/Eligibility Review Bill Of Rights:	/ Review:		· · · · ·					
	- Signed and dated by correct	parties							
	Review HIPAA: -Correct study title and info								
	-Part C addressed								
	-Part G addressed -signed and dated by correct parties								
	-Fillable fields in 14 point for of document)	t (matches rest							
	Review initial ICF(s):	UCSF Hele	en Diller F	amily					
	-consent process document -all optional sections addres	Con	nprehens	ive					
V	-signed and dated by correc	Can	cer Cente	er Inter	rnal Cha	rt Review (Checklist		
	-version correct -not expired								
	-correct study stratum (if ap	Review Notific	cation of New	v Risks:					
	-documentation of new risk update (if applicable)	- verbal notific new risk added		updated ICF w	/ith				
	-Review to ensure person co consent discussion and signi	signed by an Ir	nvestigator ar	nd was complet					
	DOA and 1572 prior to cons of the new risk(s)								
	Review any re-consents: -completed as per above	lity criteria:							
	-check against study tracker								
		-	-	rollment in tria support each	-		_		
		inclusion/exclu	usion criteria						
		-Investigator si used to suppor	-	all source docs					
		-Ensure correct		ligibility checkli eck	ist				
		-Ensure Invest and CRC sign of			e)				
		Review On-Stu	udy Content:			-	•		
		Ensure med hi clearly docume							
		Investigator Review Advers	se Event (Tox	icity Sheets), a	ind				
			and Investiga	tor signatures.					
		-Ensure Source support data o		tion is available	to				
		Review all SAE been submitte		hat they have isor, IRB, FDA, e	etc.				
		(as applicable) protocol and a							
		-Ensure Source		tion is available	e to				
	Comprehensiv	mily							
	Comprehensive Cancer Center Internal Chart Review Checklist								
								- F	Pag
	Review all labs, scans, etc. fo	or Investigator rev	iew and signa	tures:					
	-Addressed in a timely mann program guidelines)	-							
	-Abnormal values for study p graded using CTCAE and indi								
	NCS by Investigator. -CS events are documented a								
	protocol								
	Review for completeness of -within scan window	required evaluati	ons (e.g. REC	IST)					
	Ensure that GCP is followed t							1	
	(i.e., cross-outs are initialed a Ensure Off Study Treatment						-		
	and signed/dated by Investig applicable)								
	Ensure study product use by has been documented (drug								
	orders etc.) Protocol violations/ deviation	ns have been						-	
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