

Enhancing the Power of Observational Data

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External on-site data audits

- Checks performed by regional data center may confirm internal consistency of data and identify missing values
- On-site audits identify sources of error in data collection, abstraction, and representation
- Assess structure, quality and reliability of submitted data

CCASAnet Audit Schedule

CCASAnet@	Sites	Audit Date	Dataset	Auditors	# Records	# Variables	Audit Project
		Sep 24-26, 2007	HIV	CCM, SND	31	930	Baseline audit
		Nov 5-7, 2007	HIV	CCM, SND	18	400	Baseline audit
		Jul 30-Aug 1, 2007	HIV	CCM, SND	26	1634	Baseline audit
		Apr 9-11, 2007	HIV	SND (CCM, JN)	17	321	Baseline audit
		Apr 7-8, 2008	HIV	CCM, SND, DRM	33	975	Baseline audit
		Apr 21-22, 2008	HIV	CCM, SND, DRM	29	587	Baseline audit
		Jul 9-11, 2007	HIV	CCM, SND	35	1927	Baseline audit
		May 7-8, 2008	HIV resubmission	CCM, SND	26	463	Re-audit
		Mar 15-18, 2010	Cancer, TB, AIM1	CCM, SND, JW	59	3209	Cancer/TB data, Dual-audit
		Nov 9-11, 2009	Cancer, TB	CCM, SND	24	1215	Cancer/TB data
		Aug 19, 2010	AIM1	CCM	27	567	Dual-audit project**
		Dec 14-16, 2009	Cancer, TB	CCM, SND	27	970	Cancer/TB data
		May 3-5, 2010	Cancer, TB, AIM1	CCM, SND	56	2036	Cancer/TB data, Dual-audit
		Nov 2-5, 2009	Cancer, TB	CCM, SND	24	1504	Cancer/TB data
		Jan 25-27, 2010	Cancer, TB	CCM, SND	19	1102	Cancer/TB data
		Oct 1-15, 2012	VDOC Merged Data	BES, AKP, FHW	136	9299	VDOC self-audit
		Jul 17-19, 2013	HIV	CCM, SND	31	3384	Baseline audit*
		Mar 18-20, 2013	HIV, CE	CCM, SND	43	3018	Core + New data
		Apr 28-30, 2014	CE, TB, Cancer, HPV	CCM, SND	30	880	Core + New data
		Sep 23-25, 2013	HIV, CE	CCM, SND	34	2359	Core + New data
		Apr 1-3, 2013	HIV, CE, Peds	CCM, SND	28	1992	Core + New data
		Jun 17-19, 2013	HIV, CE, TB, Cancer, Peds	CCM, SND, OS	60	3285	Core + New data
		Dec 10-12, 2012	CE, TB, Cancer, HPV	CCM, FHW	24	3199	Core + New data
		Feb 25-27, 2013	HIV, CE	SND, AKP	30	1755	Core + New data
		May 30-Jun 3, 2014	HIV, TB, Cancer, Peds	CCM, SND, OS	73	4070	Re-audit + New data
		Aug 18-21, 2014	HIV, CE, TB, Cancer, HPV	CCM, SND	50	2263	Re-audit + New data
		Jul 21-24, 2014	CE, TB, Cancer, Peds	CCM, SND, OS	79	6361	Re-audit + New data
Totals	13 clinics	27 unique visits	62 datasets	9 auditors	1069 records	59705 vars	

Core Data Tables

tblBASIC	tblFOLLOW
PATIENT BIRTH_D SITE CENTER MALE_Y MODE MODE_OTH HIVDIAGNOSIS_D FIRSTVIS_D ENROL_D RECAR_Y RECAR_D RECAR_ID AIDS_Y AIDS_D EDUCATIONYEARS EDUCATION_OTH EMPLOYED_Y MARITAL_STATUS BIRTH_MODE	PATIENT DROP_Y DROP_D DROP_RS DROP_OTH DEATH_Y DEATH_D AUTOP_Y DEATH_R1 DEATH_OTH1 DEATH_RC1 L_ALIVE_D DEATH_MOTHER_Y DEATH_MOTHER_D DEATH_FATHER_Y DEATH_FATHER_D OTHER_STORY

Required, 1 row per patient

tblVISIT
PATIENT VISIT_D LOCATION WEIGHT WEIGHT_U HEIGHT HEIGHT_U CDCSTAGE WHOSTAGE DISCLOSURE_STATUS

tblCE
PATIENT CE_Y CE_D CE_ID CE_OTH CE_WD STATUS_ID STATUS_D STATUS_OTH

tblART
PATIENT ART_ID ART_SD ART_ED ART_RS_START ART_RS_START_OTH ART_RS_STOP ART_RS_STOP_OTH ART_DO ART_FR

tblMED
PATIENT MED_ID MED_OTH MED_SD MED_ED MED_RS_START_OTH MED_RS_STOP_OTH MED_DO MED_FR

tblHPV_CERVICAL
PATIENT CERV_DX_D CERV_TEST_TYPE CERV_RESULTS_PAP CERV_RESULTS_PAP_OTH CERV_RESULTS_COLPO CERV_RESULTS_COLPO_OTH CERV_RESULTS_BIOPSY CERV_RESULTS_BIOPSY_OTH CERV_HP_V_STATUS CERV_HP_V_RESULTS CERV_HP_V_SUBTYPES CERV_TX CERV_TX_OTH CERV_TX_D CERV_CONDY CERV_CONDY_TX CERV_CONDY_TX_OTH CERV_CONDY_TX_D

tblCE_CANCER
PATIENT CANCER_TYPE CANCER_OTH CANCER_D CANCER_CERTAINTY CANCER_EXTENT CANCER_TREATMENT

tblCE_TB
PATIENT TBDIAGNOSIS_D CXPOS_Y AFBPOS_Y PCRPOS_Y GENEXPRTPOS_Y MODSPOS_Y OTHERPOS_Y INHRESISTANCE_Y RIFRESISTANCE_Y PYRRESISTANCE_Y EMBRESISTANCE_Y TBSITE TUBERCULINPOS_Y TBPVENTIVE_Y TBTX_INIT TBTX_INIT_OTH TBTX_INIT_STOP_D TBTX_CONT TBTX_CONT_OTH TBTX_CONT_STOP_D TBTX_INTERMITTENCY RECEIVINH_Y

tblHPV_ANAL
PATIENT ANAL_DX_D ANAL_TEST_TYPE ANAL_RESULTS_PAP ANAL_RESULTS_PAP_OTH ANAL_RESULTS_SCOPE ANAL_RESULTS_SCOPE_OTH ANAL_RESULTS_BIOPSY ANAL_RESULTS_BIOPSY_OTH ANAL_HP_V_STATUS ANAL_HP_V_RESULTS ANAL_HP_V_SUBTYPES ANAL_TX ANAL_TX_OTH ANAL_TX_D ANAL_CONDY ANAL_CONDY_TX ANAL_CONDY_TX_OTH ANAL_CONDY_TX_D

tblLAB
PATIENT LAB_D LAB_ID LAB_V LAB_U LAB_F LAB_ST

tblLAB_RNA
PATIENT RNA_D RNA_V RNA_U RNA_T

tblLAB_CD4
PATIENT CD4_D CD4_V CD4_P

Notes:

- This quick reference lists the commonly used tables of the CCASAnet Common Data Model/Data Transfer Standard. See the DTP document for specs on the Additional Tables.
- Each patient must have one and only one row in tblBASIC and tblFOLLOW.
- Patients can have multiple rows in all other tables.
- The _A variable (date approximation) is available for every _D (date) variable (see DTP page 4).

Additional Tables:

tblLAB_BP
 tblLAB_HB
 tblLAB_HEP
 tblLAB_VIRO
 tblART_MOTHER
 tblCLINICALTRIAL

Source documents



Audit outcomes

Most common data errors observed:

- Incorrect ART regimens and start and stop dates
- Measurements and data found in the clinical record but not included in the research database
- Laboratory values with no source documents
- Capture of clinical endpoints very challenging

Perceived reasons for data errors

- Doctors' handwriting
- Access to archived files
- Completeness of charts
- Original lab slips/results not retained
- Ability to retain well-trained abstractors

Benefits of data audits

- Useful data quality control for both regional data coordinating center and local sites
- Promote confidence in the shared dataset among network investigators
- Provide sites with an estimate of their data quality at baseline and over time
- Allow for the identification and resolution of weaknesses in data prior to analyses
- Lead to quality improvement interventions including self-audit programs

Application of data audit results

- Source data verification is considered the gold standard for quality assessment of clinical research data but is costly and time-consuming
- Degree to which low quality data affects outcomes of observational research studies has not been established
- Planned analyses using pre- and post-audit data to assess impact of data errors and data quality activities (auditing) on study estimates