



CRP Administrator: IPEC Reports

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Agenda

- What/who is Institutional Performance Evaluation Committee (IPEC)
- Performance Scoring
- Implications of Substandard Scores
- IPEC Reports
- Future Performance Criteria
- Questions

IPEC: Members

Chair: Ellis Levine, MD (Roswell Park)

Vice Chair: Lisa Jacobs, MD (Johns Hopkins)

Members: Barbara Barrett, Sherry Breaux, Jenny Darcy, Shauna Hillman, James Urbanic, MD (UCSD)

Dan Sargent, Trini Ajazi, Marcia Kelly

IPEC: Charge

- IPEC is charged with ensuring that Alliance member institutions meet high quality standards in the conduct of clinical research and the protection of human subjects
- IPEC evaluates 3 primary areas: quality, timeliness (based on studies in RAVE) and participation

IPEC: Timeline

IPEC evaluates member networks twice a year

- Reports are generated ~ 2 months prior to Group meeting
- IPEC meets to review the reports 4 - 6 weeks prior to Group meeting
- IPEC presents recommendations to the Board at least 30 days prior to Board meeting at Group and reports/recommendations are sent to the PI and Lead CRP of each network
- Board votes on recommendations at Group

Overall Score

- The overall score is derived from the scores of the individual parameters
- An overall score can range from -14 to +15
- Substandard score: < 0

Implications for institutions with substandard scores

Criteria for warnings of substandard institutional performance

Prior to a recommendation for probationary status the IPEC may issue warnings to institutions with substandard overall scores of **-1 to -5** during one evaluation period.

Criteria for recommendation of probation of Main member networks

The IPEC may recommend probation to the Membership Committee if a network meets *one* of the criteria below.

- Two successive evaluation periods with substandard overall scores of **-3** or less.
- One evaluation period with substandard overall score of **-6** or less.
- Three successive evaluation periods with substandard scores of **-2** for timeliness.

Implications for institutions with substandard scores

Probation Sanctions:

- Immediate: PI loses voting rights if he/she has a seat on the Board of Directors
- Year 1 Anniversary: Accrual limitation (15 patients or 50% of average which ever is greater)
- Year 2 Anniversary: Board of Directors may vote to terminate membership

IPEC Reports: Overview

*Alliance Institutional Network Evaluation Report
 Report for Network {network NCI ID}
 For Current Year: March 1, 2015 to February 29, 2016
 Data as of February 29, 2016*

Member Name	Prior Overall Score	Current Overall Score	Quality Score ** (Value**)						Timeliness Score ** (Value**)			Group Part Score ** (Value**)	Accrual All Trials (Rave Trials)
			Inelig	IRB Audit*	Pharm Audit*	Pt Case Audit*	Spec Cond	Early Term	Data Sub	Queries	Baseline Specimen		
[name of network]	NA	5	-1 (4%)	2 (A)	0 (ANFU)	0 (ANFU)	1 (100%)	1 (0%)	-2 (69%)	1 (85%)	2 (100%)	1 (Yes)	33 (30)

*A=Acceptable, ANFU=Acceptable Needs Follow-up, U=Unacceptable
 NA: No data to evaluate

Metrics for current reporting period
 Range (-5, 15)
 25th Percentile = 2
 50th Percentile = 4
 75th Percentile = 7
 90th Percentile = 8



IPEC Reports: Overall Scores

Member Name	Prior Overall Score	Current Overall Score
[name of network]	NA	5

- Two successive evaluation periods with substandard overall scores of **-3** or less.
- One evaluation period with substandard overall score of **-6** or less.

IPEC Reports: Quality

Quality Score ** (Value**)					
Inelig	IRB Audit*	Pharm Audit*	Pt Case Audit*	Spec Cond	Early Term
-1 (4%)	2 (A)	0 (ANFU)	0 (ANFU)	1 (100%)	1 (0%)

IPEC Reports: Quality - Ineligibility

Quality Score ** (Value**)					
Inelig	IRB Audit*	Pharm Audit*	Pt Case Audit*	Spec Cond	Early Term
-1 (4%)	2 (A)	0 (ANFU)	0 (ANFU)	1 (100%)	1 (0%)

Parameter	Values	Points
Ineligibility (% of patients with eligibility review completed that were deemed ineligible) i.e.: # patients ineligible / # patients evaluated	>3%	-1
	1-3%	0
	<1%	1
NOTE: This includes all patients evaluated who were enrolled on Alliance trials in RAVE (patients are not filtered by date of registration to the trial).		

IPEC Reports: Quality - Ineligibility

- All patients enrolled in Alliance studies are evaluated by the Data Manager to verify eligibility.
- Ineligibility is confirmed by review performed by the Study Chair
- Lead CRP and CRA assigned to the study in RAVE receive a communication from the Data Manager

Ineligible Patient Notification

Notification for Your Records

TO:
FROM: Data Manager
DATE: 4/18/2016
RE: A011106, 9103XXX, ZZ

This case has been deemed ineligible on X/XX/15 due to ultrasound of diseased breast being performed outside of eligibility window, violating protocol section 4.2.

Refer to the protocol for guidance on how to proceed with patient care and forms submission. Follow your internal procedures for reporting the violation at your site.

If you have any questions, please feel free to contact me. Thank you for your assistance.



IPEC Reports: Quality - Audit

Quality Score ** (Value**)					
Inelig	IRB Audit*	Pharm Audit*	Pt Case Audit*	Spec Cond	Early Term
-1 (4%)	2 (A)	0 (ANFU)	0 (ANFU)	1 (100%)	1 (0%)

Parameter	Values	Points
Main Member Audit (for each component--IRB, pharmacy, patient case, the most current audit results of acceptable, acceptable needs follow-up (ANFU) or unacceptable will be evaluated)	Unacceptable	-2
	ANFU	0
	Acceptable	2

IPEC Reports: Quality - Audit

- Last audit or re-audit if report is completed 2 months prior to Group meeting
- If audit was satisfactory then will be included on the IPEC until the next audit occurs (up to 3 years)
- Unacceptable audit results will remain on IPEC report until re-audit occurs and is finalized

IPEC Reports: Quality – Specimen Condition

Quality Score ** (Value**)					
Inelig	IRB Audit*	Pharm Audit*	Pt Case Audit*	Spec Cond	Early Term
-1 (4%)	2 (A)	0 (ANFU)	0 (ANFU)	1 (100%)	1 (0%)

Parameter	Values	Points
Specimen Condition (% of samples intact out of all samples received) i.e.: # baseline samples received intact during the report period / # baseline specimens received during the report period	<97%	-1
	97-99%	0
	>99%	1

IPEC Reports: Quality – Specimen Condition

- If the repository selects any status other than acceptable (i.e. thawed, damaged) the CRA that logged the specimens will receive an email stating the shipment was received but there was a problem with the specimen(s)
- The CRA can also log into BioMS to check the receipt status

IPEC Reports: Quality – Specimen Condition

Dear BioMS User,

Shipment #47[REDACTED] shipped on 05/05/2016 has been received at the **Alliance Biorepository at Washington University in St. Louis** but there were complications with some specimen(s) contained in this shipment. A list of problematic specimens and reasons are given below. Please review the specimen status in the BioMS application check-list view or contact the biorepository for further instructions. (Click the specimen URL to view details)

Specimen expected : [4.5ml EDTA Plasma \(3x1.5ml\)](#)
Collection date : 5/5/16 10:17 AM
Study : A011106-ST1
Epoch,Arm,Collection event : On Therapy A011106-ST1,All,Week 4 (Cycle 2, Day 1 +/- 3 days)
Receive quality : Thawed

Specimen expected : [4.5ml No Additive Serum \(3x1.5ml\)](#)
Collection date : 5/5/16 10:17 AM
Study : A011106-ST1
Epoch,Arm,Collection event : On Therapy A011106-ST1,All,Week 4 (Cycle 2, Day 1 +/- 3 days)
Receive quality : Thawed

If there are questions about the shipment or the specimens the repository can be contacted, contact details given below.

Contact Person : Coordinator ACOSOG
Contact Phone : (314) 454-7615
Contact Email : tbank@wudosis.wustl.edu

Thanks,
BioMS Support
Email: BioMSHelp@bmi.wustl.edu Phone: 1-(855)-55-BIOMS/1-(855)-552-4667



IPEC Reports: Quality – Early Termination

Quality Score ** (Value**)					
Inelig	IRB Audit*	Pharm Audit*	Pt Case Audit*	Spec Cond	Early Term
-1 (4%)	2 (A)	0 (ANFU)	0 (ANFU)	1 (100%)	1 (0%)

Parameters	Values	Points
Early termination of follow-up (% of patients deemed lost to follow-up, withdrew consent for follow-up or deemed canceled, i.e., protocol treatment not received) i.e.: # patients that terminated follow-up early / # patients that were accrued by the membership	>3%	-1
	1-3%	0
	<1%	1
NOTE: This includes all patients accrued by the membership on RAVE trials (patients are not filtered by date of registration to the trial).		

IPEC Reports: Timeliness

Timeliness Score ** (Value**)		
Data Sub	Queries	Baseline Specimen
-2 (69%)	1 (85%)	2 (100%)

IPEC Reports: Timeliness – Data Submission

Timeliness Score ** (Value**)		
Data Sub	Queries	Baseline Specimen
-2 (69%)	1 (85%)	2 (100%)

Parameters	Values	Points
Data submission (% of eCRFs submitted on time) i.e. # forms received on time during report period / total of # forms that were due during the time period plus # forms due <u>before</u> the time period that are still outstanding Baseline and treatment forms are given a 15-day grace period after the target date. Follow up forms are given a 30-day grace period after the target date.	<75%	-2
	75%-80%	-1
	80%-85%	0
	85%-90%	1
	>90%	2

IPEC Reports: Timeliness – Data Submission

- Lead CRPs and CRAs have access to Overdue Reports for the sites in which they are rostered

IPEC Reports: Timeliness – Data Submission

Welcome

ANNOUNCEMENTS

Three Investigators Receive Funding Awards Through Alliance Cancer Control Program

Three Alliance researchers and junior investigators have been selected to receive annual funding awards to support their work through the Alliance NCI Community Oncology Research Program (NCORP) Research Base, which is supported by the NCI Division of Cancer Prevention (DCP) and administered through the Alliance Cancer Control Program (CCP). The annual awards include the **Alliance Cancer Control Program Pilot Project Award** and **Alliance Cancer Control Program Junior Faculty Award**.

PILOT PROJECT AWARD

William Wood, MD, MPH (University of North Carolina at Chapel Hill)

"Assessing physical fitness in cancer patients with cardiopulmonary exercise testing and wearable data generation: An Alliance pilot study proposal"

JUNIOR FACULTY AWARD

Eric Roeland, MD (UCSD Moores Cancer Center)

Mentor: **Charles Loprinzi, MD** (Mayo Clinic)

"A prospective pilot study to evaluate and correlate early lean muscle loss with functional activity in metastatic gastrointestinal and lung cancer patients"

Ashley Rosko, MD

Mentor: **Michelle Naughton, PhD** (Ohio State University Comprehensive Cancer Center)

Quick Links

- Alliance Directory
- Audit Resources
- Bibliography (Alliance Publications)
- BioMS
- Contact Us
- CRP Resources
- Frequently Used Documents
- Delinquency/Overdue Reports
- Legacy Sites
- Meetings
- Meeting Presentations & Materials
- OPEN
- Policies & Procedures
- RAVE
- Recent Postings
- Study Summaries
- Tools & Calculators

IPEC Reports:

Timeliness – Data Submission

CTSU: Data Quality Portal (DQP)

- The Data Quality Portal (DQP) is a single platform accessed via the CTSU Website providing access to query and form delinquency information for all CTEP Rave studies, including the ability to link directly to Rave forms for management of data.
- RAVE CRA role is needed to access DQP
- Release date: Fall 2016

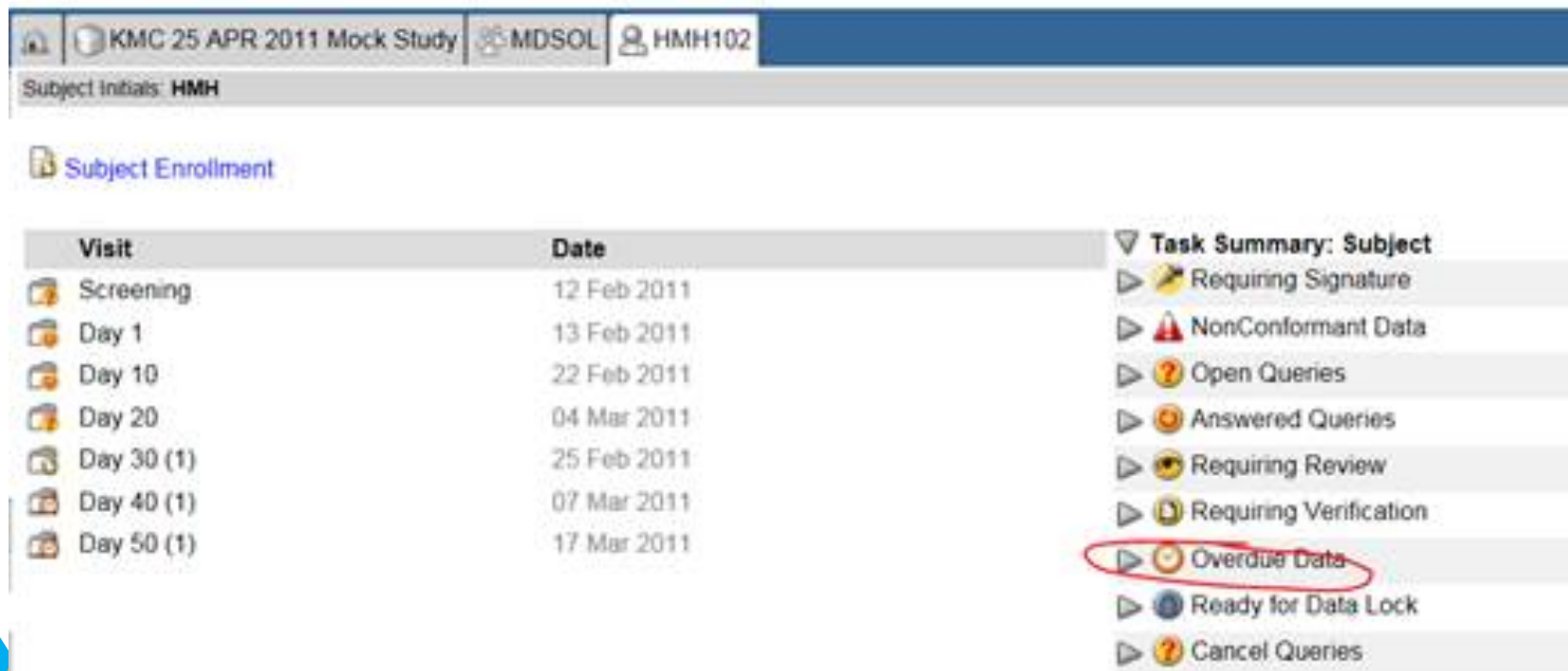
IPEC Reports: Timeliness - Queries

Timeliness Score ** (Value**)		
Data Sub	Queries	Baseline Specimen
-2 (69%)	1 (85%)	2 (100%)

Parameter	Values	Points
Response to Queries (% of issued queries that were resolved on time) i.e. # query responses received on time during report period / total of # query responses that were due during the time period plus # query responses due <u>before</u> the time period that are still outstanding Queries are given a 15 day grace period after the issue date.	<75%	-2
	75%-80%	-1
	80%-85%	0
	85%-90%	1
	>90%	2

IPEC Reports: Timeliness - Queries

- Queries are automatically generated as soon as a form has been saved.



The screenshot displays a user interface for a clinical trial system. At the top, a navigation bar shows the study name 'KMC 25 APR 2011 Mock Study', the user 'MDSOL', and the subject 'HMH102'. Below this, the subject's initials 'HMH' are displayed. A section titled 'Subject Enrollment' contains a table of visits and a task summary.

Visit	Date
Screening	12 Feb 2011
Day 1	13 Feb 2011
Day 10	22 Feb 2011
Day 20	04 Mar 2011
Day 30 (1)	25 Feb 2011
Day 40 (1)	07 Mar 2011
Day 50 (1)	17 Mar 2011

To the right of the table is a 'Task Summary: Subject' section with a list of tasks:

- Requiring Signature
- NonConformant Data
- Open Queries
- Answered Queries
- Requiring Review
- Requiring Verification
- Overdue Data** (highlighted with a red circle)
- Ready for Data Lock
- Cancel Queries

IPEC Reports: Timeliness – Baseline Specimen

Timeliness Score ** (Value**)		
Data Sub	Queries	Baseline Specimen
-2 (69%)	1 (85%)	2 (100%)

Parameter	Values	Points
Specimen Submission (% of baseline samples received on time) i.e. # specimens received on time during report period / # specimens that were due during the time period 60 day grace period after due date	<75%	-2
	75%-80%	-1
	80%-85%	0
	85%-90%	1
	>90%	2

IPEC Reports: Timeliness – Baseline Specimen

- BioMS will be enhanced with the capability for a CRA to run a report for a patient showing what specimens still needed
- Specimens are being logged in at the time of receipt
- New hire: Melissa McKenna will be responsible for monitoring specimen submissions and reaching out to sites to resolve overdue specimens

IPEC Reports: Participation

Group Part Score ** (Value**)
Audit
1 (Yes)

Parameter	Values	Points
Audit participation by physicians and clinical research professionals (CRPs) in the past two years	No participation	0
	MD or CRP participated	1

IPEC Reports: Participation

- Investigators and CRPs can volunteer to participate in audits by contacting Barbara Barrett (bbarrett@uchicago.edu) or Joshua Lachewitz (jlachewitz@uchicago.edu)
- Considerations Audit Team make when scheduling volunteer auditors:
 - Travel expense
 - Specialty/expertise
 - Volunteer's schedule

IPEC Reports: Participation

"The APC will work diligently to allow a variety of ad-hoc auditors to participate in Alliance audits. However, Alliance Audit Policies and Procedures or feasible audit expenses will not be altered to accommodate a network wishing to earn a performance point. "

IPEC Reports: Accrual

Accrual All Trials (Rave Trials)
Cur Year
33 (30)

- Accrual represents the enrollment to treatment trials credited to the Alliance. This does not represent membership accrual credits.
- RAVE accrual represents enrollment to treatment trials that are in RAVE.

IPEC: Site Level Detail

*Alliance Institutional Network Evaluation Report
 Information for Affiliates of Sorted Alphabetically by CTEP-ID (Under Parent)
 For Current Year: March 1, 2015 to February 29, 2016
 Data as of February 29, 2016*

Location Name	Location CTEP-ID	Parent Name	Parent CTEP_ID	Patients Ineligible	Patients Evaluated	Percent Ineligible	Patients Withdraw Consent	Patients Lost to Followup	Patients Early Study Termination	Patients Accrued on Rave Trials	Percent Patients Early Termination	Forms On Time	Forms Expected	Forms Percent On Time	Query Responses On Time	Query Responses Expected	Query Percent On Time	Current Year Accrual All Trials	Current Year Accrual on Rave Trials
				na	na	na	na	na	na	0	na	na	na	na	na	na	na	0	0
				na	na	na	na	na	na	0	na	na	na	na	na	na	na	0	0
				na	na	na	na	na	na	0	na	na	na	na	na	na	na	0	0
				na	na	na	na	na	na	0	na	na	na	na	na	na	na	2	0
				0	0	0%	0	0	0	1	0%	0	0	0	30	30	100%	2	1
				na	na	na	na	na	na	0	na	na	na	na	na	na	na	0	0
				0	6	0%	0	0	0	6	0%	77	77	100%	78	94	83%	5	4
Membership Totals				0	6	0%	0	0	0	7	0%	165	171	96%	157	176	89%	9	5

Future Performance Criteria

- RT
- Imaging



Who to contact

Questions regarding specific network IPEC reports:

Marcia Kelly
Membership@AllianceNCTN.org

