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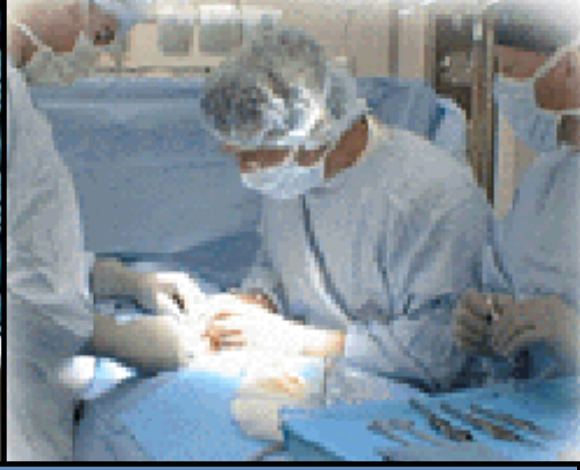

A Common Clinical Data Management System (CDMS) for the Cooperative Groups

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

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Presentation Purpose and Outline

- Purpose: Provide a status update regarding an NCI initiative to modernize and standardize a critical component of the Cooperative Group infrastructure (i.e. CDMS)

- Outline
  - Establishing the Vision for a common CDMS for the Groups
  - Approach/organization to the project
  - Project status

Establishing the Vision

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What is a Clinical Data Management System (CDMS)?

- Tool(s) or processes that support:
  - Data collection
    - Remote Data Capture (RDC)
  - Data coding
    - Standard libraries - Common Toxicity Criteria (CTCAE)
  - Data management
    - Discrepancy, delinquency, communication, correction
  - Preparation of data for analysis

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A CDMS directly/indirectly effects the entire research organization

Areas effected:

- Science
- Safety
- Regulatory
- Administration
- Operations
- Financial management

Individuals effected:

- Group Chair
- Statistical office
- Operations office
- Study principal investigator (PI)
- Participating sites/research staff
  - Physicians, nurses, CRAs
- Patient

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Types of CDMS

Paper

- Types:
  - Mail/Fax; Double data entry
  - Scan (Object Identifier)
- Pros:
  - Minimal set-up time/effort
- Cons:
  - Double data entry
  - 'Dumb' forms require more time/effort to complete Inc. risk of data discrepancy/delinquency
  - Difficult to maintain CRF version control
  - Communication occurs 'outside' system

Electronic

- Types:
  - Custom
  - Commercial off the shelf (COTS)
- Pros:
  - Simplify CRF version control
  - 'Smart' forms simplify data collection
  - Upfront edit checks reduce of data discrepancy/delinquency
  - Communication occurs within system
- Cons:
  - Set-up time/effort

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Group CDMS History

- At one time all Groups used paper CDMS
- Incremental shift by individual Groups to electronic CDMS (Custom and COTS). Some still use paper.
- Inter and Intra Group variability with approach to CDMS
- ~2006:
  - Groups agree to work together to implement a common CDMS
  - Groups perform an independent analysis of available COTs products (select Rave)
- ~2009: CBIIT RFP (select Rave)
- 2010: Initiate NCI common CDMS for Groups

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Effect of multiple CDMS's on the Group clinical trial system

- Increased training costs
- Increased risk of data delinquency and/or discrepancy
- Increased time/effort to correct/complete data
- Longer to get the Science and Safety results of a trial

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The Need

- IOM report states: More resources for the rapid implementation and adoption of a common electronic registration and data capture system would increase consistency across trials, conserve resources by:
  - Reducing the workload associated with patient enrollment and follow-up
  - Allow for more timely review of the data from a trial
  - Enhance the knowledge gained from a trial
  - Standardized case report forms would ease the burden of regulatory oversight and lead to better compliance*

*A National Cancer Clinical Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group Program: Sharyl J. Nass, Harold L. Moses, and John Mendelsohn, *Editors*; Committee on Cancer Clinical Trials and the NCI Cooperative Group Program; Institute of Medicine; Copyright © 2010

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Opportunity

- A strong foundation for CDMS uniformity across the Groups
  - Investigators/sites are often members of multiple Groups
  - All Group site/investigators can enroll patients on selected clinical trials through the CTSU
- Added emphasis
  - Federal funding constraints make it essential for sites to perform clinical trial functions with optimal efficiency
  - Transformation/consolidation of Groups
    - Further promotion of network collaboration
    - Merged Groups must select a common CDMS

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The Vision for a Common Group CDMS

Re-enforce focus on Science and the Patient

NOT data management

- Promote efficient and accurate data entry using a common intuitive/user-friendly interface
- Scalable for use for all Group Trials
  - Treatment (drug, surgery, radiation); Prevention; Cancer Control; Diagnostic
- Minimize training and implementation cost across Groups through shared training and experience
- Reduce data management burden/costs for multi-center coordinating center as well as participating sites

A Common CDMS for the Cooperative Groups

Project Approach/Organization

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Requirements to deploy a common CDMS to the Groups

Standard approach to:

- Application (Medidata Rave): *Complete*
- Core Configuration: *Complete*
- Business practices: *Ongoing*
  - Data delinquency rules
- Integration with 'Global' applications: *Ongoing*
  - Pt enrollment, NCI accrual and adverse event reporting, User-name/password/Role (single sign-on)
- Case Report Forms: *Ongoing*
  - Cancer Data Standards Registry and Repository (caDSR)

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Thoughtful approach to Standardization (One-size fits all)

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Key Concepts for Successful Deployment

- Leverage experience
  - Medidata
  - Groups
    - General CDMS
    - Rave Specific: Alliance (2yr) and NCIC (5+yr)
- Strive for common look/feel of outward/community facing features
  - Remote data capture (RDC)
- Standard interfaces require a standard approach
- Communication…communication…communication

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The Cast

- Adopting organizations
- NCI
- Contract support

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Organizations Adopting Common CDMS

- Who:
  - All NCI Cooperative Groups
  - COG Phase 1 Consortium
  - Adult Brain Tumor Consortium (ABTC)
  - Theradex (early phase 1)
  - Cancer Trials Support Unit (CTSU)
- Role:
  - Modify business, operational and technical infrastructure to implement Rave
  - Participate in standards development/adoption activities
  - Integrate local applications with Rave
  - “Local” knowledge acquisition

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NCI

- Who
  - CTEP, DCP, CCCT, RRP, CIP, BRB, CBIIT
- Role
  - Project oversight
  - Establish overall direction and expectations
  - Promote standardization NOT standards
  - Resource allocation:
    - License
    - Hosting
    - Training
    - Maintenance
    - Contractor support

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Contract support

- Who/Role
  - CTSU (Westat/Coalition)
    - CDMS Support Center (CSC), IT integration, Training funding & logistics support
  - Capital Technology Information Systems (CTIS)
    - IT integration for CTEP applications
  - ESSEX
    - Working group lead, CBIIT coordination support
  - Medidata
    - Hosting, Knowledge transfer, Training, consulting services, Rave URL, Maintenance, Help-desk

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CDMS Support Center (CSC)

- Location – CTSU
- Representation:
  - NCI, Westat; Coalition; Medidata; Group Consultants
- Role:
  - Central management for NCI Rave implementation
  - Coordinate efforts for uniform deployment
  - Oversight of day to day activities
  - Coordinate working groups and training

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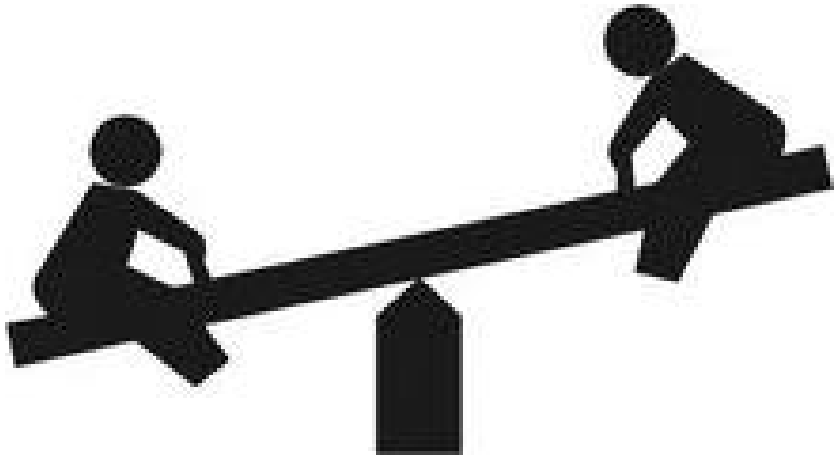
Balancing Act: Network vs. Local Challenges



Network

Local (Adopting Organization)

Use <u>Working Groups</u> to identify and develop Standards and/or best business practices

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Working Group Areas

Priority One

(Required for launch)

- Core configuration
- Validation
- Data quality
- Data elements (i.e. eCRFs)
- Study build
- Study conduct
- User Management
- Integration

Priority Two

(start fall 2011)

- Metrics
- RDC Training
- Auditing

Priority Three (tbd)

- Reporting
- Stat issues - Analysis/Deviations
- Ancillary studies

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Working Groups Governance

- Coordinated and facilitated by Co-Leads (at least one Group co-lead)
- Individual group charters to define the governance, goals and deliverables
- Each organizations has one voting member to make recommendations on behalf of their organization
- Membership
  - At least two NCI reps
    - Focus on big picture, 'Push standardization, NOT standards'
  - At least two CTSU reps
  - One or more reps from each Cooperative Group

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Communication Plan

- Working Groups
- Leadership Committee
  - NCI, Contractor, One rep/Group
- Training
- Face-to-face meetings
- Monthly newsletter

A Common CDMS for the Cooperative Groups

Project Status

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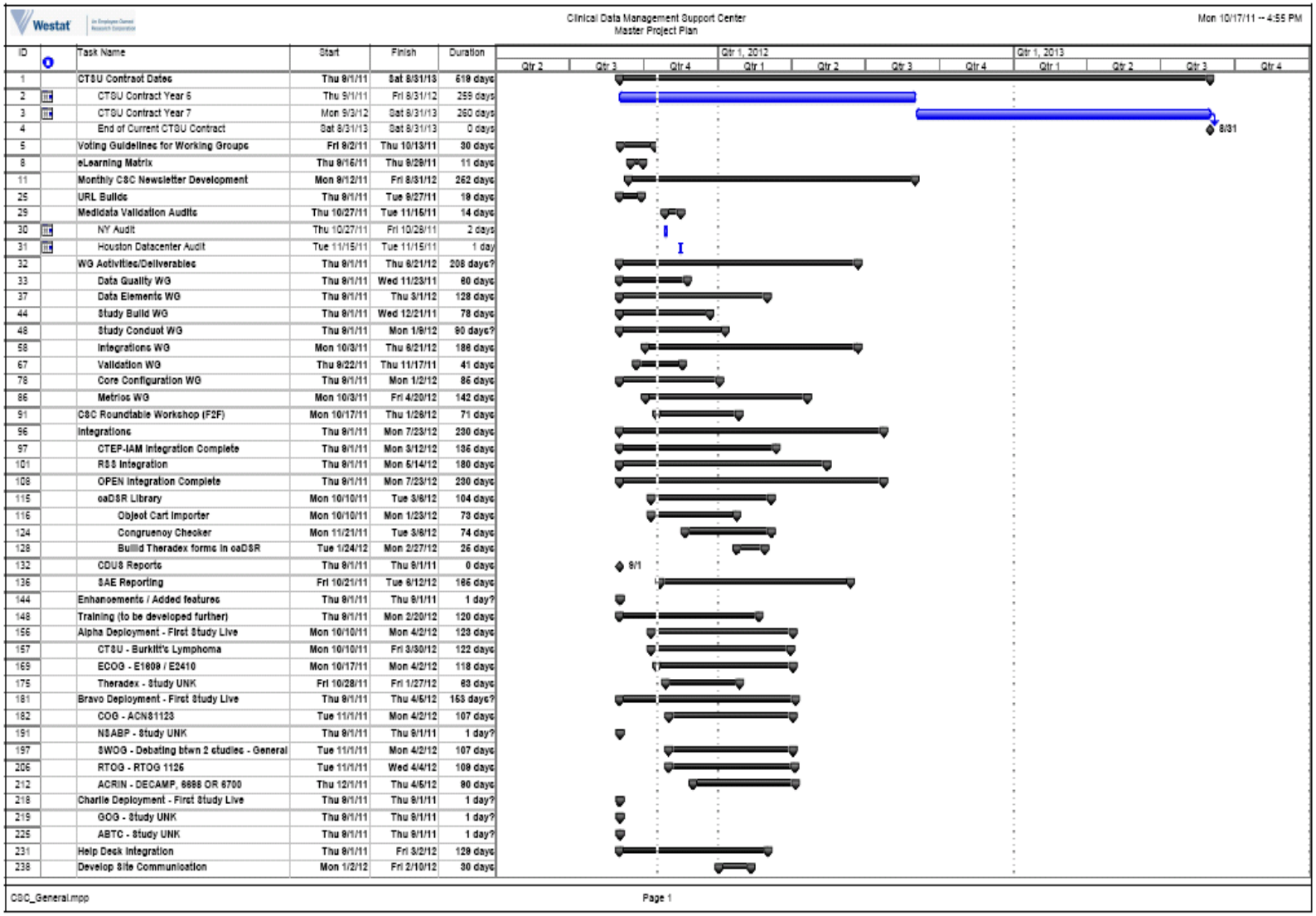
Project Plan/Timeline



ID	Task Name	Start	Finish	Duration
1	CTSU Contract Dates	Thu 8/1/11	Sat 8/31/13	618 days
2	CTSU Contract Year 6	Thu 9/1/11	Fri 8/31/12	259 days
3	CTSU Contract Year 7	Mon 9/3/12	Sat 8/31/13	260 days
4	End of Current CTSU Contract	Sat 8/31/13	Sat 8/31/13	0 days
5	Voting Guidelines for Working Groups	Fri 8/2/11	Thu 10/13/11	30 days
8	eLearning Matrix	Thu 9/15/11	Thu 9/29/11	11 days
11	Monthly CBC Newsletter Development	Mon 8/12/11	Fri 8/31/12	262 days
25	URL Builds	Thu 8/1/11	Tue 9/27/11	18 days
29	Medidata Validation Audits	Thu 10/27/11	Tue 11/15/11	14 days
30	NY Audit	Thu 10/27/11	Fri 10/28/11	2 days
31	Houston Datacenter Audit	Tue 11/15/11	Tue 11/15/11	1 day
32	WG Activities/Deliverables	Thu 8/1/11	Thu 8/21/12	208 days?
33	Data Quality WG	Thu 8/1/11	Wed 11/23/11	80 days
37	Data Elements WG	Thu 8/1/11	Thu 3/1/12	128 days
44	Study Build WG	Thu 8/1/11	Wed 12/21/11	78 days
48	Study Conduct WG	Thu 8/1/11	Mon 1/9/12	90 days?
58	Integrations WG	Mon 10/3/11	Thu 8/21/12	188 days
67	Validation WG	Thu 9/22/11	Thu 11/17/11	41 days
78	Core Configuration WG	Thu 8/1/11	Mon 1/2/12	86 days
86	Metrics WG	Mon 10/3/11	Fri 4/20/12	142 days
91	CBC Roundtable Workshop (F2F)	Mon 10/17/11	Thu 1/26/12	71 days
96	Integrations	Thu 8/1/11	Mon 7/23/12	230 days
97	CTEP-IAM Integration Complete	Thu 8/1/11	Mon 3/12/12	136 days
101	RSS Integration	Thu 8/1/11	Mon 5/14/12	180 days
108	OPEN Integration Complete	Thu 8/1/11	Mon 7/23/12	230 days
115	caDSR Library	Mon 10/10/11	Tue 3/6/12	104 days
116	Object Cart Importer	Mon 10/10/11	Mon 1/23/12	73 days
124	Congruency Checker	Mon 11/21/11	Tue 3/6/12	74 days
128	Build Theradex forms in caDSR	Tue 1/24/12	Mon 2/27/12	26 days
132	CDUS Reports	Thu 8/1/11	Thu 8/1/11	0 days
136	SAE Reporting	Fri 10/21/11	Tue 6/12/12	166 days
144	Enhancements / Added features	Thu 8/1/11	Thu 8/1/11	1 day?
148	Training (to be developed further)	Thu 8/1/11	Mon 2/20/12	120 days
156	Alpha Deployment - First Study Live	Mon 10/10/11	Mon 4/2/12	123 days
157	CTSU - Burkitt's Lymphoma	Mon 10/10/11	Fri 3/30/12	122 days
169	ECOG - E1608 / E2410	Mon 10/17/11	Mon 4/2/12	118 days
175	Theradex - Study UNK	Fri 10/28/11	Fri 1/27/12	63 days
181	Bravo Deployment - First Study Live	Thu 8/1/11	Thu 4/5/12	153 days?
182	COG - ACNS1123	Tue 11/1/11	Mon 4/2/12	107 days
191	NSABP - Study UNK	Thu 8/1/11	Thu 8/1/11	1 day?
197	SWOG - Debating btwn 2 studies - General	Tue 11/1/11	Mon 4/2/12	107 days
206	RTOG - RTOG 1126	Tue 11/1/11	Wed 4/4/12	108 days
212	ACRIN - DECAMP, 6688 OR 6700	Thu 12/1/11	Thu 4/5/12	90 days
218	Charlie Deployment - First Study Live	Thu 8/1/11	Thu 8/1/11	1 day?
219	GOG - Study UNK	Thu 8/1/11	Thu 8/1/11	1 day?
225	ABTC - Study UNK	Thu 8/1/11	Thu 8/1/11	1 day?
231	Help Desk Integration	Thu 8/1/11	Fri 3/2/12	128 days
238	Develop Site Communication	Mon 1/2/12	Fri 2/10/12	30 days

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Group Deployment Plan (start 4/1/11)

Stage 1
0 to 90 days

- Start Apr 1, 2011
- First 3 sites (Alpha) begin deployment (start of stage)
  - Allow 1yr to implement

Stage 2
91 to 180 days

- Start Jul 1, 2011
- Second 3 sites (Bravo) begin deployment (start of stage)
  - 9-months to implement
- Alpha sites continue deployment activities

Stage 3
181 to 270 days

- Start Oct 1, 2011
- Third 3 sites (Charlie) begin deployment (start of stage)
  - 9-months to implement
- Bravo sites continue deployment activities
- Alpha sites complete deployment (end of stage)

Target completion Alpha/Bravo stage 3/31/12
Charlie stage 6/30/12

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NCI Training Support for Rave deployment

- Medidata Rave curriculum
  - On-line
  - Face-to-face
- 'Train the Trainer' philosophy
- NCI, through the CTSU, provides:
  - Logistical support (scheduling, invitations and assure full classrooms)
  - Training and travel costs
    - Fundamental and mid-level: ~200 individuals
    - Advanced training: ~100 individuals
    - Additional training/sessions: Groups pay. CTSU will provide logistical support

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Working Group Status

- Data Elements
  - Establish CRF governance model for caDSR
  - Establish conventions for computer to computer communication
  - Identify enhancements to Object Cart Importer to pull CRFs from caDSR to Rave
- Data Quality
  - Creating a report shell for CRF timeliness and Query timeliness
  - Provided recommendations to classifying standards for Protocol Deviations
- Study Conduct
  - Identify standard procedures/communication
  - Design standard process for Lost to Follow-Up and Edit Checks

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Working Group Status

- Study Build
  - Designing a standard Medidata Rave specific study build workflow
  - Exploring optimal methods of folder design in Medidata Rave
- Rave Validation
  - Write validation test cases
  - Medidata Rave site audits
    - Confirm Disaster recovery and back-up procedures/capabilities
- Core Configuration
  - Created and documented standard Medidata Rave Core Configuration

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Rave Integration Prioritization

- Priority One (necessary for implementation)
  - caDSR (case report form source)
  - Establish single sign-on
    - Identify and Access Management (IAM)
    - Regulatory Support System (RSS)
    - Oncology Patient Enrollment Network (OPEN)
- Priority two (within first 3 to 6 months of implementation)
  - NCI reports
  - Serious Adverse Event Reporting system
- Priority three (tbd)
  - Auditing
  - NCI reports+++

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Severe Adverse Event (SAE) Reporting for Cooperative Groups

- Problem: Currently there is a dis-connect between 'Routine' Adverse Event (RAE) and Severe Adverse Event (SAE) reporting
  - RAE and SAE data captured in separate systems
  - Double data entry
  - Promotes under/over reporting
  - Discrepancy Reconciliation

- Solution: Single source for reporting both RAE and SAE reporting (i.e. Rave)
  - Enter AE one time (reduce/eliminate discrepancies)
  - 'Smart' CRFs identify AEs that require additional information (SAEs)
  - Reduce training requirements for site MD, RN, CRAs

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Post-Implementation Support

- Forum to share experiences: telecon & face-to-face
- Expand/Maintain global library (caDSR)
- Expand integration efforts
  - New (SAE and Audit systems)
  - Enhancements (scalability of NCI reports)
  - Maintenance
- Procurement issues (hosting, ancillary software)
- Potential expansion to additional adopting multi-center organizations
  - DCP & CTEP Phase 2 contracts?
  - PBTC?

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Conclusion - Modernized/Standardized Group CDMS will:

- Promote transformation of Groups into a ‘Network’
- Meet FDA requirements for electronic data capture and transfer
- Reduce effort/cost of data management
- Improve trial management/decision making
- Promote data sharing
- Sets the stage for potential further infrastructure improvements
  - SAE reporting; Remote auditing; electronic NDA

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Questions for CTAC

- Suggestions regarding how to promote Rave rollout to Group membership?
- If/when/how to expand the initiative beyond the Groups?
- Suggested metrics-of-success of interest?

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Questions/Items for discussion?