CDMS Integration Experience

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Overview

- Planning and Training
- Integrations
  - Payment System
  - Patient Data Expectancy and Institution Performance Reports
- Challenges
  - Duplicate reporting of Adverse Events
  - Collecting supporting documentation
  - Building studies in the new CDMS has required us to adjust many of our processes

Planning and Training

Planning

- **Working Groups**
- **Face to Face Meetings**
  - **Helpful to hear about the work that other LPOs were doing**
- **Internal Planning Sessions**
  - **Reimagine our study build processes**
  - **New roles**
  - **Redistribution of work**

Training

- How many staff? - 20 (most training went to ~12)
- How many classes? - 20
  - Often out of town
- How many hours? - 1085
- Some staff spent 22 full days

- 145 person days devoted to training in new CDMS

Integrations

An overview of how we adapted our existing systems to function with the new CDMS.

Payment System

- Our reimbursements are calculated by triggers.
  - Triggers often require submission of multiple CRFs and supporting documents.
- Must enforce complex business rules when calculating payments.
- Payments driven by data assembled from multiple sources.
  - NSABP Coordinator Online
  - NSABP Legacy System
  - New CDMS
- Payment system updated to run from Data Warehouse.

Payment System

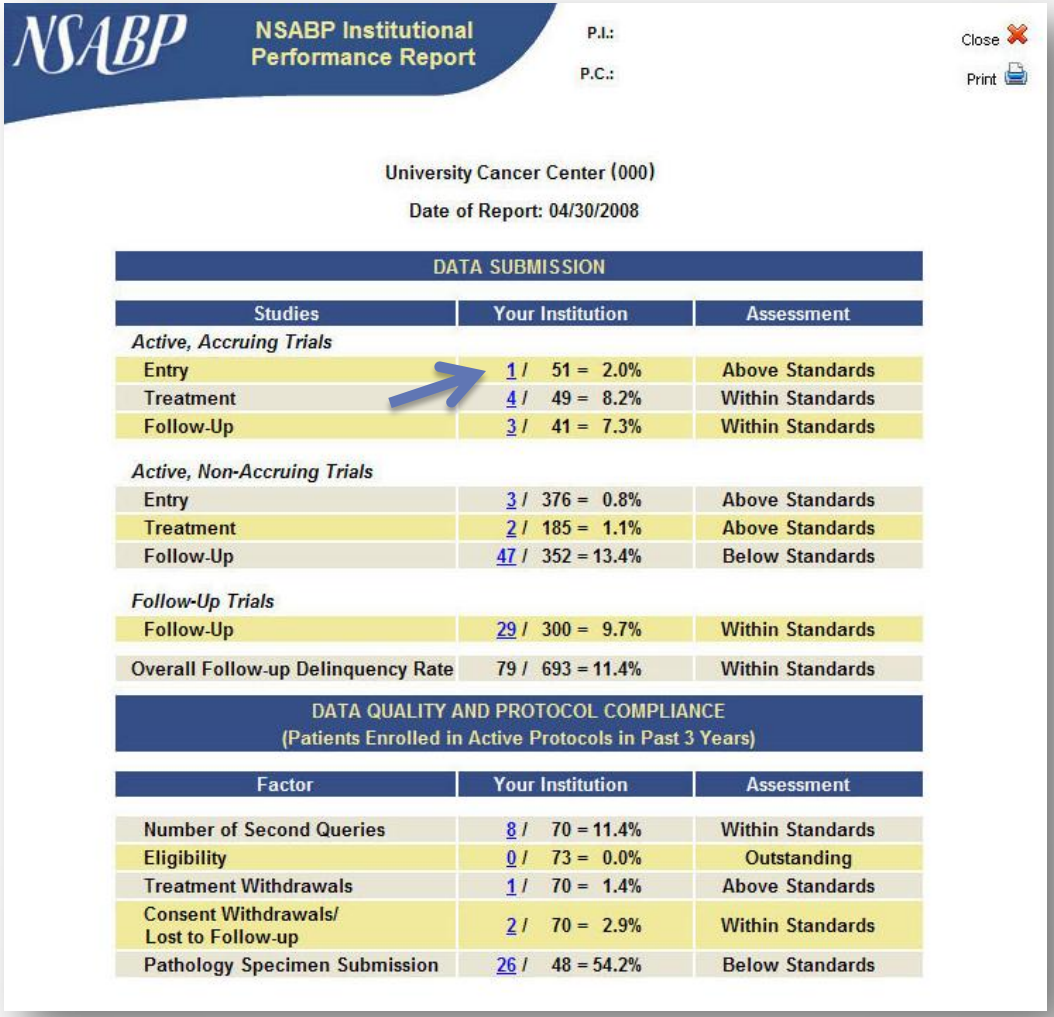
- **Clinical Data is extracted from new CDMS using Web Services.**
- **The data is then transformed and stored in our local database.**
- **Data is then periodically loaded into our data warehouse.**

Expectancy Reporting

- **Currently provide member institutions with cross-protocol reports.**
  - **Status of data submission overall and by patient**
  - **Institution and site performance reports**

- **We plan to continue this reporting for trials regardless of the electronic data capture system in use.**

Performance Report



NSABP Institutional Performance Report

P.I.:

P.C.:

Close

Print

University Cancer Center (000)

Date of Report: 04/30/2008

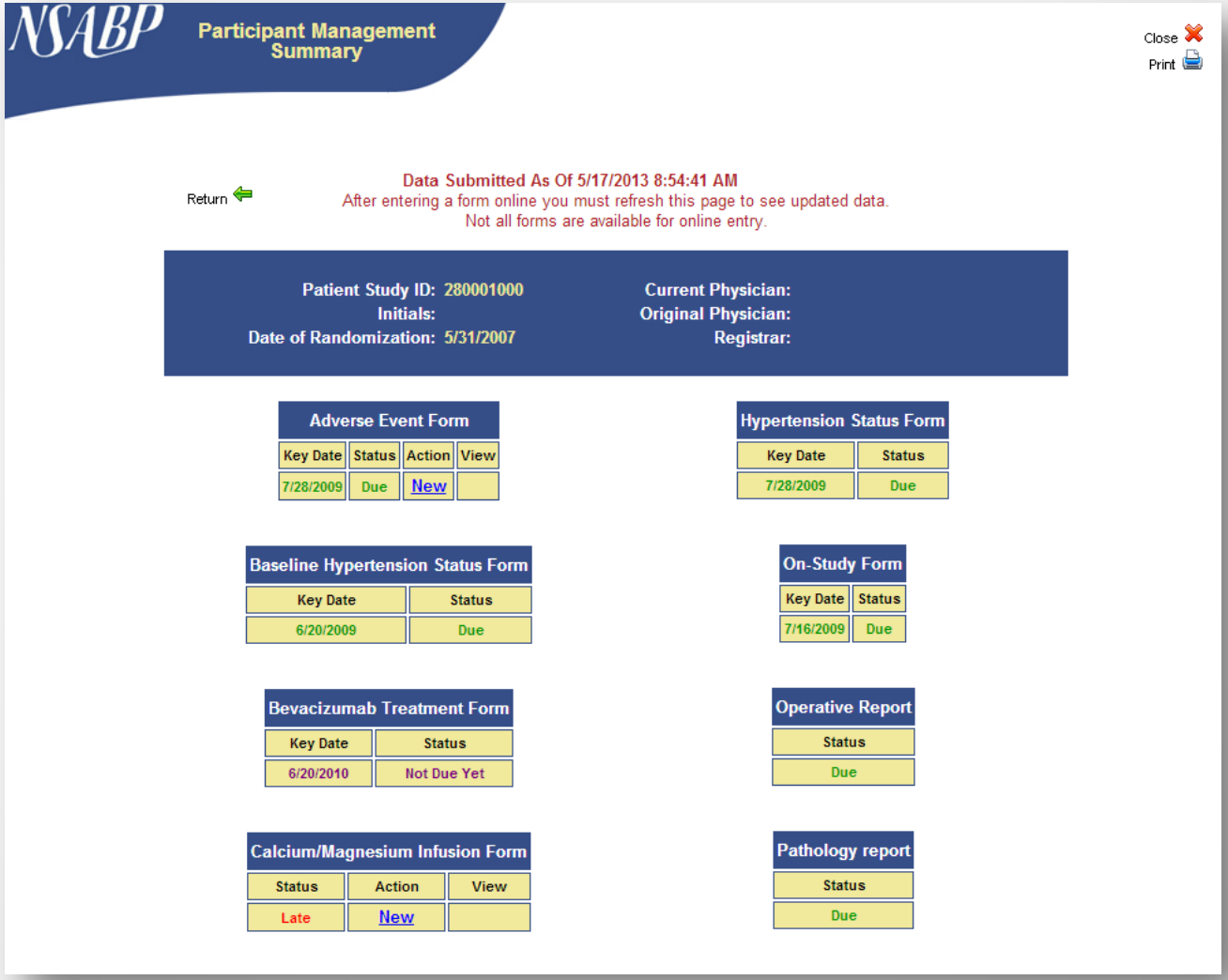
DATA SUBMISSION

Studies	Your Institution	Assessment
Active, Accruing Trials		
Entry	1 / 51 = 2.0%	Above Standards
Treatment	4 / 49 = 8.2%	Within Standards
Follow-Up	3 / 41 = 7.3%	Within Standards
Active, Non-Accruing Trials		
Entry	3 / 376 = 0.8%	Above Standards
Treatment	2 / 185 = 1.1%	Above Standards
Follow-Up	47 / 352 = 13.4%	Below Standards
Follow-Up Trials		
Follow-Up	29 / 300 = 9.7%	Within Standards
Overall Follow-up Delinquency Rate	79 / 693 = 11.4%	Within Standards

DATA QUALITY AND PROTOCOL COMPLIANCE
(Patients Enrolled in Active Protocols in Past 3 Years)

Factor	Your Institution	Assessment
Number of Second Queries	8 / 70 = 11.4%	Within Standards
Eligibility	0 / 73 = 0.0%	Outstanding
Treatment Withdrawals	1 / 70 = 1.4%	Above Standards
Consent Withdrawals/ Lost to Follow-up	2 / 70 = 2.9%	Within Standards
Pathology Specimen Submission	26 / 48 = 54.2%	Below Standards

Participant Management Summary



Expectancy Reporting

- **This requires programming of expectancy calculations in our system and in the new CDMS.**
  - **Duplicated effort**
  - **Difficult to ensure that expectancy calculations are the same in both systems**
  - **Clinical data from the new CDMS must be available to our existing reporting software.**

- **Benefits > Costs**

Challenges

A discussion of our initial difficulties in adopting the CDMS

Adverse Event Duplicate Reporting

- Our current practice is to prevent entry of Adverse Events that require expedited reporting on our CRFs.
- Users are prompted that the AE should have been reported via AdEERS and does not need to be double reported.
- Our Medical Oversight nurses perform reviews on all AEs reported via AdEERS.
- We merge the reviewed AdEERS reported AEs with the routinely reported AEs from our CRFs.
- Our statisticians use the merged data when doing their analysis.

Adverse Event Duplicate Reporting

- **We have found it difficult to collect AEs in the way that we would like using the CDMS.**
  - **New CDMS user interface and performance issues are currently contributing to our concerns.**

- **At this time, we felt that we could not also introduce the complexity required to prevent duplicate reporting.**

- **We have also not yet planned for how we will integrate the new CDMS with our medical review processes.**

Supporting Documentation

- **We collect supporting documentation which we use for review, expectancy, and payment purposes.**

- **Current process:**
  - **Prompts user to submit supporting documentation at time of CRF completion including a tracking sheet. We store in the database that we are expecting documentation for that particular CRF.**
  - **When the documentation arrives at the Biostatistical Center, our database and document management system are updated.**
  - **Our expectancy and payment systems are now able to include the supporting documentation in their calculations.**
  - **Data management and medical oversight are also able to easily find the documentation in our document management system.**

Supporting Documentation

- **Challenges**
  - **The new CDMS does not natively support programmatic handling of supporting documentation, a feature that we require.**
  - **The processes available in the new CDMS require significantly more manual effort than in our existing system.**
  - **We do not have a way to extract the supporting documentation en masse or programmatically from the new CDMS into our document management system.**

Building Studies

- **Form Design**
  - **Characteristics of the new CDMS requires breaking up existing NSABP standard forms into many smaller forms.**
    - **Inability to have more than one set of repeating questions on a given CRF**
    - **Lack of skip pattern functionality**

- **Edits**
  - **Edit definition language in new CDMS differs from how we write edits.**
  - **Cross-form edits are more difficult in new CDMS.**
  - **Unable to use our mature system of testing edits.**

Building Studies

- **Object Cart Importer (OCI)**
  - **The NCI requirement to curate data elements in caDSR adds to the project timeline.**
  - **Variable names assigned by caDSR and used in the new CDMS are unwieldy.**
  - **The lack of cohesion between caDSR and new CDMS causes issues in form building.**
    - **Lack of "check all that apply" functionality in new CDMS means that log forms must be built.**
  - **OCI downtime halts the import of revised forms into new CDMS.**

Final Thoughts

- **We have expended a tremendous amount of time and resources in planning and training.**

- **We have been able to build some integrations with our existing systems but we are just beginning. We will need to continue to work towards attaining the same level of robustness that we achieved in our own system.**