CTN / CRA Workshop

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Topics

- Audits
- Monitoring
- Performance Reports
- Electronic Signatures
- Protocol Deviations

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Audits

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Audits

Due to the COVID-19 pandemic, many audits were delayed.
We are now conducting several remote audits using:

1. **Access to your EMR system**
2. **Access to a shared portal**
   (e.g. Box, Docushare, another document storage system)
3. **E-mailed, deidentified charts**
4. **A combination of the above**

Through June, we have conducted **10 full audits*** remotely.
*This does not include re-audits of regulatory and pharmacy, as these are usually conducted remotely.

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Audits

New portal for loading patient case documents on the CTSU website:

1. Under "Auditing and Monitoring" tab, there is a "Source Document Portal" link.
2. You will add documents for the cases selected by NRG Oncology.
3. Can redact PHI ahead of time, or in the portal.

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Audits

Pharmacy audit includes using video chat
(Facetime, Teams, Skype, etc.).
   ○ Photos with telephone conversation are a last resort.
   ○ Need to schedule a time with the pharmacist.

Regulatory and Drug Log Review to be conducted prior
to the audit, at the NRG Oncology SDMC,
as done previously.

To allow for preparation, and to lessen the burden, we
are not selecting unannounced cases for remote audits.

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Multi-Group Audits

Brief Description:

- Involves 2 LPOs at a time.

- CTSU sent Facilitator, who initially corresponded with you.

- Separate final reports and a separate exit interview, conducted in one room, for LPOs involved.

- 12 have been scheduled or conducted since onset of pilot audits in 2017 (program initiation in 2016).

- 12% of eligible audits underwent an MGA.

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Multi-Group Audits

- **April 2020, NCI decided to not go forward with the program; Pilot complete.**

- Resulted in other programs:
  - NCI Auditor training
  - Found consistency among groups

- You can still request a multi-group audit and we will work with the other groups to arrange this.

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Auditors

NRG Policy that Auditors need not provide personal Information (SSN, DOB).

- We are representatives of NCI.

- We are registered with NCI.

- We complete required CTMB training, as well as NRG training, GCP and Human Subject training.

- We sign confidentiality agreements.

- Informed consents allow access to records.

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Monitoring

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Monitoring

GY004, GY005	BR004, GI004, LU005
RAVE	**Monitoring Portal on CTSU** Includes detailed consent content review

GY018	B-55
Monitoring Portal for Eligibility In-house review at 5 months	**Monitoring Complete** Was in-house, included detailed consent content review

BR003
Canada Only (in-house)   Carbo use is investigational

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Performance Reports

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Institution Performance Reports

- Reports are sent to Contact PI and Lead RA every 3 months (quarterly).

- "Preview" reports are also sent to Lead RA one (1) month prior to every quarterly report.
  - This provides opportunity to resolve questions by reviewing advanced copy.

REPORT

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Institution Performance Reports

Six Tabs (Spreadsheets):

Performance Summary	Delinquency by Site
Accrual by Protocol	Accrual by Site
Form Details	Query Details

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Institution Performance Reports

UPDATES/NEWS:

- Delinquency is now based upon total # forms and total # queries ("new" denominator), as opposed to basing on # patients with a form or # patients with a late query ("old" denominator).

- Newer metric of "completeness," which replaced the patient-based counts. This shows the % of patient cases with any late forms or late queries.

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Institution Performance Reports

DATA SUBMISSION

Number of forms not yet received, divided by the total number of forms expected over the past three years, for all sites within the network.

DATA QUERIES

Number of queries outstanding, divided by the total number of queries expected over the past three years, for all sites within the network.

COMPLETION

The number of patients with an outstanding form or query, divided by the number of patients with at least one form or query expectancy, over the past three years.

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Institution Performance Reports

Continuing to send during the COVID-19 pandemic:

" *We are continuing to provide you with your Institution Performance Reports to assist you in monitoring your data submission.*

Given the current circumstances related to COVID-19, we recognize that performance related to accrual and data submission will likely be negatively affected and this will be taken into consideration as we evaluate your institution. "

- We have also removed the "Network Assessment" and "Network Score" during this time.

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Institution Performance Reports

The **most recent report** covered 162 NRG studies, and nearly 580,000 forms. (*The CTSU DQP covers only 58 NRG studies*)

	Quarterly Reports (1/1/2019 – 4/1/2020	Preview Report 6/1/2020
% forms delinquent	4.8%	5.3%
Avg. # forms per Network Assessment	2917	2941
% queries delinquent	29.0%	29.2%
Avg. # queries per Network Assessment	126	103

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Institution Performance Reports

General Comments:

- Once delinquent form is submitted, system updated, and next report credited.

- Be aware of the sites/institutions in your network – get in touch if you disagree.

- Be aware of your patients – get in touch with us regarding "missing" or "extra" patients.

- Use this as a tool to communicate with your network sites.

- Send specific questions to *support@nrgoncology.org*.

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Electronic Signatures

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Electronic Signatures

- Protocol NSABP B-55 is next on the list.

- Request will be for Physician listed on the IRB approval submission.

- Will re-invite Physicians
  - May be necessary to delegate to other Physician (contact us).

- Physicians will have to do basic RAVE training (Medidata Classic Rave EDC Essentials for Investigators).

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Electronic Signatures

- Can sign off one time for entire patient (not each form).

- Sites (PI and RAs) will be contacted via e-mail when data is deemed appropriate for sign-off.

- Current site following the patient(s) signs off as they have RAVE access.

- We will keep you updated via broadcasts and training materials.

- If access issue encountered for PI, contact *support@nrgoncology.org* for assistance.

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Protocol Deviations

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Protocol Deviations Due to Covid-19

- All deviations (Major and Minor) reported to NRG Oncology.

- Continue to report Major deviations to the IRB of record.

- **Refer to the March 23, 2020 Memorandum from Drs. Meg Mooney and Worta McCaskill-Stevens of NCI located on CTSU.**

NRG Oncology COVID-19 Updates   ×
All of our SDMC and Operations Center staff have shifted to work remotely, and remain here to serve you.
NRG Oncology has pulled together a webpage to collate COVID-19 information for patients as well as for our researchers and research staff at our sites.

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ONCOLOGY   Contact Us   News   Member Login   Search...
Advancing Research. Improving Care™   For Patients ▾   Clinical Trials ▾   Scientific Program ▾   About Us ▾   Resources ▾   Support NRG

- Can also find this on NRG Oncology website main page…
  Click on "**COVID-19 Updates**."

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Protocol Deviations

A PROTOCOL DEVIATION OCCURS…

If any protocol-directed instructions are not followed, regardless of the reasoning why.

A deviation usually translates to an audit deficiency.

A PROTOCOL DEVIATION IS NOT…

When there is leeway in the protocol (e.g., wording of "recommended").

CAPA is usually required for Major deviations (send to IRB of record) but may not be required for COVID-19 related deviations.

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Protocol Deviations Due to Covid-19

Procedure immediately instituted for legacy systems and RAVE studies:
Email the appropriate Data Manager with the information and the Data Manager will add to the appropriate RAVE form.

New Procedure for Active RAVE studies:
1. Use the Add-event feature on the subject home page.
2. Once added, the form will appear in a "COVID-19" folder.
3. Can add deviations to the single form for a patient.

Protocols not in RAVE:
Continue to e-mail Data Manager.

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Protocol Deviations

NCI / CTSU INITIATIVE - NRG Will Pilot:

- One form per patient in RAVE (can add > 1 deviation per patient).

- Site completes form in RAVE.
  - Descriptive drop-downs for deviation type (similar to audit deficiencies).

- LPO review, with the following options:
  - Request more information.
  - Sign off as complete.
  - Determines that it is not a deviation.

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