Welcome to the ECOG-ACRIN Virtual Town Hall for Community Physicians

Purpose of the Town Hall

• Link to broad ECOG-ACRIN Community – what can EA do to help
• Information Exchange
• Bidirectional – Q/A now and future

Reminders

• Please make sure your microphone is muted and your camera is off.
• If you have questions during the presentation, please submit them via email to TownHall@ecog-acrin.org. We will address during the call, if time allows. Otherwise, we will respond to you following the call.
Brief Agenda

• Introduction: EA Operations Support and Guidance  
  Peter J. O’Dwyer, MD

• COVID-19: Trial Adaptation & Regulatory Implications  
  Bruce Giantonio, MD

• Remote Consent Process  
  Matthias Weiss, MD

• COVID-19 Emotional Support Resources  
  Lynne Wagner, PhD

• Association of Community Cancer Centers (ACCC) Feedback  
  Al B. Benson, MD

• COVID-19-Related Q & A  
  Mitchell D. Schnall, MD, PhD

• Adjourn
Overview of Operations Support and Guidance
March 17, 2020: ECOG-ACRIN Central Offices in PHL and BOS converted all staff to remote work

- Telecommuting equipment deployed, VPN connections established for 200+ employees
- All SOPs reviewed and adjusted to accommodate remote work environments
- Announcement to EA Community with email listservs made public to ensure smooth transition and continued communication
- Main phone lines re-routed to remote receptionists
- Fax machines converted to fax servers for remote access
- Additional communication tool deployed to remote staff (Skype for Business)
ECOG-ACRIN Operations

• EA COVID-19 Advisory Team formed
  – Dedicated email listserv created to answer questions, track responses, develop FAQ
    – EACOID19@ecog-acrin.org

• Weekly calls with NCTN and NCORP leadership to discuss concerns/address issues

• Guidance documents released from NCTN, NCORP and FDA to assist sites with regulatory concerns and patient management

• Additional announcements from Central Laboratories and Study-Specific Guidance

• Protocol-specific deviation guidance documents in process
ECOG-ACRIN Group Meeting

- April 29 – May 1, 2020 Meeting not proceeding as planned (in person or virtually)
  - Committee Chairs may hold 2 – 3 hour webcast committee meetings over the summer – we want community participation
  - Potential for F2F Leadership Retreat in late September with Committee Chairs/Co-Chairs
- Fall 2020 Meeting (Wednesday, October 21 – Friday, October 23, 2020) in Fort Lauderdale, FL proceeding as planned (F2F)
General Issues/Concerns with Respect to the Novel Coronavirus Outbreak
- **General Landscape:** All Cancer Treatment is a Deviation in this Environment

- **Research Questions Relevant to Patients and Caregivers**
  - Question about Immunotherapy Dosing:
    - Consideration of Q6wk dosing of pembrolizumab as acceptable deviation from Q3wk dosing of pembrolizumab prescribed in the protocols
  - Interventions to Protect Health Care Workers

- **Natural History Study from NCI Projected**

- **Accrual for the NCTN by Group from 2/3/2020 to 3/29/2020**
NCTN Accrual for “Intervention” Step in Trials by Lead Group & Week February 3, 2020 to March 29, 2020 (CTSU Open Data)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ALLIANCE</td>
<td>93</td>
<td>88</td>
<td>83</td>
<td>93</td>
<td>105</td>
<td>94</td>
<td>67</td>
<td>30</td>
<td>-66%</td>
</tr>
<tr>
<td>CCTG</td>
<td>2</td>
<td>5</td>
<td>5</td>
<td>4</td>
<td>6</td>
<td>3</td>
<td>6</td>
<td>4</td>
<td>-10%</td>
</tr>
<tr>
<td>COG</td>
<td>43</td>
<td>53</td>
<td>47</td>
<td>45</td>
<td>51</td>
<td>58</td>
<td>41</td>
<td>34</td>
<td>-30%</td>
</tr>
<tr>
<td>ECOG-ACRIN</td>
<td>45</td>
<td>56</td>
<td>47</td>
<td>51</td>
<td>45</td>
<td>45</td>
<td>43</td>
<td>35</td>
<td>-26%</td>
</tr>
<tr>
<td>NRG</td>
<td>44</td>
<td>57</td>
<td>44</td>
<td>59</td>
<td>45</td>
<td>46</td>
<td>49</td>
<td>24</td>
<td>-51%</td>
</tr>
<tr>
<td>SWOG</td>
<td>49</td>
<td>46</td>
<td>43</td>
<td>54</td>
<td>54</td>
<td>46</td>
<td>54</td>
<td>35</td>
<td>-29%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>276</td>
<td>305</td>
<td>269</td>
<td>306</td>
<td>306</td>
<td>292</td>
<td>260</td>
<td>162</td>
<td>-44%</td>
</tr>
</tbody>
</table>
## NCTN Accrual for “Screening” Step in Trials by Lead Group & Week

February 3, 2020 to March 29, 2020 (CTSU Open Data)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ALLIANCE</td>
<td>24</td>
<td>22</td>
<td>25</td>
<td>28</td>
<td>22</td>
<td>27</td>
<td>13</td>
<td>7</td>
<td>-70%</td>
</tr>
<tr>
<td>CCTG</td>
<td>7</td>
<td>10</td>
<td>18</td>
<td>10</td>
<td>6</td>
<td>10</td>
<td>6</td>
<td>11</td>
<td>15%</td>
</tr>
<tr>
<td>COG</td>
<td>9</td>
<td>14</td>
<td>14</td>
<td>9</td>
<td>5</td>
<td>9</td>
<td>9</td>
<td>5</td>
<td>-49%</td>
</tr>
<tr>
<td>ECOG-ACRIN</td>
<td>17</td>
<td>9</td>
<td>15</td>
<td>14</td>
<td>15</td>
<td>16</td>
<td>13</td>
<td>6</td>
<td>-58%</td>
</tr>
<tr>
<td>NRG</td>
<td>13</td>
<td>5</td>
<td>9</td>
<td>6</td>
<td>8</td>
<td>7</td>
<td>13</td>
<td>2</td>
<td>-77%</td>
</tr>
<tr>
<td>SWOG</td>
<td>20</td>
<td>28</td>
<td>28</td>
<td>23</td>
<td>30</td>
<td>24</td>
<td>23</td>
<td>21</td>
<td>-16%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>90</td>
<td>88</td>
<td>109</td>
<td>90</td>
<td>86</td>
<td>93</td>
<td>77</td>
<td>52</td>
<td>-42%</td>
</tr>
</tbody>
</table>
COVID-19 Allowable Trial Adaptation & Regulatory Implications

Bruce J. Giantonio, MD
EA Executive Officer

Questions: EACOVID19@ecog-acrin.org
Allowable Trial Adaptation: Guidance

FDA, NCI and ECOG-ACRIN Guidance Documents posted on EA & CTSU Website:

NCI:
• 3/13/2020: NCI Memo- Interim Guidance For Patients on Clinical Trials

ECOG-ACRIN:
• 3/25/2020: Letter to ECOG-ACRIN from Peter O’Dwyer and Mitchell Schnall

FDA:

Questions: EACOVID19@ecog-acrin.org
Allowable Trial Adaptation

• Safety of study participants and site staff is the priority
  – Need to be mindful of study integrity
• Documentation:
  – Document all instances of & reasons for variance in record
• Reporting deviations to IRB
  – Minor: compiled log submitted w/ the study’s CR
  – Major: expedited reporting per local/CIRB guidelines

Questions: EACOVID19@ecog-acrin.org
Allowable Trial Adaptation: Deviations

• **Minor**: minimal impact on safety or trial integrity
  – Delays in visits or treatment
  – Data collection of secondary endpoints
  – Special imaging/lab collections/PRO collection

• **Major**: alternative procedures that will
  – Substantially impact safety
  – Compromise trial integrity
  – Affect participant willingness

Questions: EACOVID19@ecog-acrin.org
Allowable Trial Adaptation: Deviation Log

- EA Protocol Specific COVID-19 Deviation Logs
  - For EA protocols with CRs due on/after July 15, 2020

- Developing a “Master Covid-19” study in Medidata Rave
  - Sites can access their patients registered to individual EA studies and complete their protocol deviation logs
  - Might not apply to TMIST and MATCH-still under discussion
  - All deviations must be documented in the research record

Questions: EACOVID19@ecog-acrin.org
Remote Consent Process

Matthias Weiss, MD, PhD
NCI CIRB Remote Consent

3-30-2020 at ncicirb.org: “Frequently asked questions regarding COVID-19 and the CIRB”

• “Can I utilize remote consent procedures at my site?”
  – Limit contact and promote social distancing in response to COVID-19
  – CIRB approval not needed; update SSW/SIW indicating use of “Remote Consent Procedures”
  – Defined (!) “Remote Consent Procedures”
    • Send Informed Consent (IC) in advance of discussion regarding study and potential participation
    • Phone/video conferencing facilitated communication identical to an in-person meeting
    • Witness present; pre-paid, self addressed envelope included if postal mail is chosen
    • Once received, investigator signs and dates IC; documents under IC signature line: “discussed with [participant or LAR name] via [telephone or videoconferencing] on [insert date] and received signed consent [insert date]”
NCI CIRB Remote Consent

• Defined (!) “Remote Consent Procedures” continued:
  – Documentation of witness name according to site specific IC policy
  – Official date of IC is when investigator signs IC, previously signed by participant
  – Signed IC to be filed; send copy of signed IC to participant
  – No research activities related to study until all steps of this IC process are complete

• Additional concerns:
  – Postal mail vs email vs electronic IC transmission according to institutional guidelines
  – HIPAA consent and witness signature policy according to institutional guidelines
  – Do not forget to update SSW/SIW indicating use of remote consent procedures
  – ThedaCare “SOP Remote Consent” available at noreeen.wynn@thedacare.org or matthias.weiss@thedacare.org
COVID-19 Emotional Support Resources for Patients and Staff

Lynne Wagner, PhD
COVID-19: Coping with Novel Challenges and Uncertainty

\[
\text{STRESS} = \frac{\text{DEMANDS}}{\text{RESOURCES}}
\]

- **Increasing DEMANDS**
  - Novel challenges: changing work flow, disrupted routines, social distancing
  - Uncertainty: COVID unknowns, course of pandemic
- **Diminishing RESOURCES**
  - Access to PPE, staffing, medical equipment, medications
  - Less personal time
- Mitigating stress requires increasing RESOURCES and/or reducing DEMANDS
RESOURCES: Increasing Coping Repertoire

<table>
<thead>
<tr>
<th>CONTROLLABLE</th>
<th>UNCONTROLLABLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Problem-focused strategies:</td>
<td>Emotion-focused strategies:</td>
</tr>
<tr>
<td>Seek info on COVID and practice management</td>
<td>Emotional expression</td>
</tr>
<tr>
<td>Consult with colleagues</td>
<td>Cultivate compassion</td>
</tr>
<tr>
<td>Leverage resources to reduce exposure risk</td>
<td>Cognitive reappraisal</td>
</tr>
<tr>
<td>Increase personal health behaviors</td>
<td>Mindful meditation</td>
</tr>
<tr>
<td>Employ active coping and self-care</td>
<td>Distraction</td>
</tr>
</tbody>
</table>
RESOURCES: Info for Providers on Practice Management

- COVID-Ready Communication Skills: A playbook of VitalTalk Tips, Anthony Back MD
  https://docs.google.com/document/d/1uSh0FeYdkGgHsZqem552iC0KmXlgaGKohl7SoeY2UXQ/edit

- Posters/handouts on Staff well-being and self-care
  www.ics.ac.uk
RESOURCES: Self-Care for Patients and Providers

1. https://www.virusanxiety.com
2. https://www.headspace.com
3. https://www.mentalhealthapps.org/
4. Call 888-793-9355
   Monday – Friday 9 a.m. – 9 p.m. ET
   Saturday – Sunday 9 a.m. – 5 p.m. ET
Provider Well-Being on the Forefront

1) Education

2) Provider Well-being as Quality metric

3) Promote Research
Association of Community Cancer Centers (ACCC) Feedback

Al Benson, MD
What are ACCC Members Seeing in Their Programs?

- Clinical coordinators not allowed on campus
- All new trials halted
- No new accruals
- Staff redeployed or otherwise occupied
- Not a top priority now

Adapted from ACCC Post-03.27.2020 Webcast Survey
Unchanged Clinical Trials Principles

• Ensuring safety of study participants is paramount
• Continue treatment trial when possible
• Maintain good clinical practices (GCP)
• Consult sponsor and IRB
• Determine alternates for patient contact, monitoring, drug access
• Document, document, document

Refer to guidance: FDA, CTEP, NCORP, CIRB, cooperative groups, industry

From webcast: Randall A. Oyer MD, President ACCC 4/3/20
Trials Trends in Response to COVID-19

- New trials have decreased
- Some trials being cancelled
- Decreased accruals to existing trials
- Delays in completion of existing trials
- Stronger focus on continuing essential treatment trials
- New COVID-focused trials are accelerated
- Audits, on-site visits, travel, meetings suspended
- Streamlined approaches and recording of deviations
- Solutions include remote work and use of telemedicine

From webcast: Randall A. Oyer MD, President ACCC 4/3/20
What You Can Do

• Stay safe and well
• Protect your patients and your staff
• Maintain focus on clinical trial safety
• Solve problems with your sponsor and your IRB
• Document
• Take this opportunity to look forward

accc-cancer.org/COVID-19

From webcast: Randall A. Oyer MD, President ACCC 4/3/20
COVID-19 Related Question and Answer Segment

Mitch Schnall, MD, PhD
Q: Is there a pause on opening up new trials?

A: No. The activation of new trials is continuing during this time so that new protocols will be open and ready as options for patients. EA is reviewing new activations on a case by case basis, and if it makes sense, we will active the trial. However, if there are unique features in the design of the trial, we may delay activation until a later time.
Q: In the email that announced the Spring meeting cancellation, it mentions “Studies continue to be activated – in most institutions the regulatory and contract specialists are working from home, and happy to keep our studies moving forward. At many institutions, activation of new studies has been suspended, but a substantial proportion recognize the importance of the ECOG-ACRIN research options for patient care.” It sounds like ECOG-ACRIN will continue activating new studies, correct? If so, then it’s safe to assume the NCI CIRB is reviewing new studies? Or, will these have to go through a site’s local IRB?

A: The NCI Central IRB (CIRB) continues to review new studies and complete continuing reviews for trials. There is no change in the oversight and responsibilities of the CIRB.
Q: Specimen collection not impacting patient treatment. There seems to be wide variability on institutional practices on specimen collection, probably dictated by the severity of COVID-19 at their site. What is ECOG-ACRIN’s stance on that? Small sites with limited staff in the labs may face particular limitations regarding getting bio-specimens during the pandemic.

A: Sites are encouraged to obtain specimens, but it is understood during the pandemic that some specimens may be missed. Local labs that are more convenient for the patient may be an option in some situations as well. Otherwise, sites are encouraged to reach out via the EACOVID19@ecog-acrin.org email alias to confirm whether a particular specimen is critical to study outcome or patient safety. If so, then those specimens should be prioritized to obtain, even if late, rather than missed entirely. For additional information, the COVID-19 Information pages on both the CTSU and EA Members website contain all protocol-specific memos related to specimen submissions.
Q: Investigational drug pharmacists – Small satellites and rural sites potentially have only one pharmacist who can mix and dispense investigational agents. If that pharmacist is out due to illness or furlough and the drug cannot be dispensed for a cycle of treatment, would that be a MAJOR or just a MINOR deviation during the pandemic? When a site is completely dependent on one specially trained employee, it makes small sites potentially vulnerable to unavoidable deviations during the pandemic.

A: There are a few other options, though none may work in this situation. One would be to administer the investigational agent at another participating site and transfer the patient. Another may be that if the location is a satellite, perhaps the dose could be administered at the main study site, or if product stability permits, the dose could be prepared at the main study site and couriered to the satellite. If none of those options are feasible, then it may be unavoidable to miss a dose of the investigational agent. This needs to be clearly documented along with the circumstances.
Q: Can you provide guidance on data delinquencies, delays in scheduling follow-up visits, or missed procedures and assessments. How should sites document this? How will this impact performance monitoring?

A: Delays related directly to COVID-19 or related local restrictions should be clearly documented as such. While some of these are considered deviations, the association to COVID-19 will be taken into account. While CIRB or local IRB may require submission of deviations more frequently, EA is requesting that deviation logs related to COVID-19 be submitted within one month after the period when COVID-19 guidance is in effect (currently June 14th 2020, subject to change).

With respect to impact on performance monitoring, EA will not be conducting the Quarterly Performance Monitoring scheduled to be run for the Spring 2020 quarter. An announcement about this will be released this week.
Q: We’ve received guidance about dispensing IP, suggestions for alternative delivery methods, etc. How should sites handle IP returns since it requires greater levels of interaction and therefore, exposure?

A: For documenting patient compliance, it may be permissible for the patient to count the medication at home while on video chat, take pictures of empty bottles, or take pictures of diaries to text or email to the site. The substitute method used to monitor compliance should be documented in the records.

Re: IP return, please contact EACOVID19@ecog-acrin.org
Q: Should sites anticipate delays in study reimbursements? Can you speak to how this will affect both NCORPs/LAPs and main member sites?

A: NCORP, LAPs and Main Member Sites should not anticipate any delays in study reimbursements coming from ECOG-ACRIN.
Q: I know the NCI doesn’t get involved with research HIPAA procedures, but I am curious to know if sites are obtaining HIPAA waivers from their Privacy Board.

A: Please refer to the latest guidance from HSS as limited waivers of HIPAA Sanctions as being permitted due to the National Public Heath Emergency

Q: Remote consenting – it seems it is allowed, but the NCI CIRB guidelines say the Responsible Investigator needs to conduct the entire consent process and have a witness present during the call. The witness would presumably be a CRA or research nurse. This is different than what the Delegation of Tasks Log allows, those allow for a designee (such as a CRA or research nurse) to be delegated to conduct the informed consent process. If the investigator is expected to go through the entire consent form remotely instead of allowing a CRA or research nurse to do that, it might discourage investigators from consenting patients remotely – especially if the process requires an investigator to conduct the entire process and have a witness there for the whole discussion. What is ECOG-ACRIN’s policy regarding remote consenting?

A: The investigator OR DESIGNEE can conduct the remote consent process, however, sites should follow their standard practice.

EA supports the remote consent process utilizing telemedicine to assist in the patient consent process. This work practice requires a potential patient to receive a copy of the consent in advance of the consent discussion. The consent must be signed by the patient and the researcher leading the consent discussion (dates do not need to be the same but the patient needs to sign first). A witness should be present but is not mandated per FDA guidance. A detailed consent note in the patient’s research file is also required to document the process.
Questions: EACOVID19@ecog-acrin.org