Clinical trial improvements, thanks to COVID-19

Research Advocacy Network
Advocate Link CONNECT

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Deborah Collyar
President
Patient Advocates in Research

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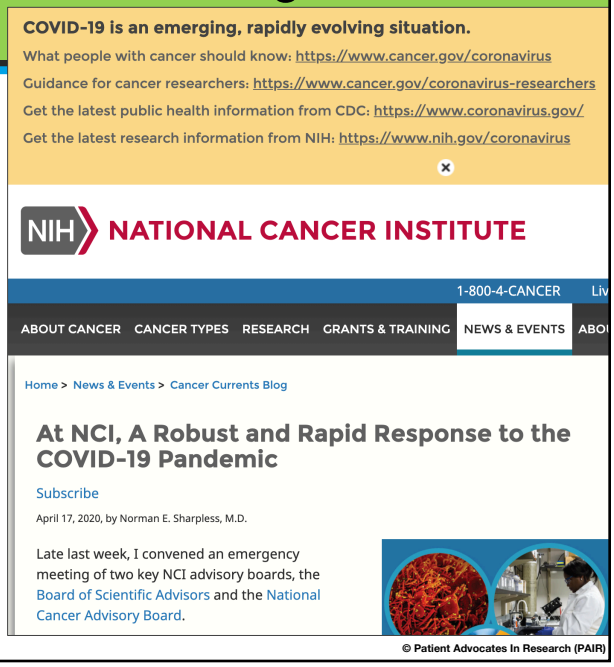
Quick review of sanctioned trial changes (NCI, NIH, FDA)

- Changes for conducting clinical trials for
  - Regulators
  - Sponsors
  - Vendors (e.g. CROs)
  - Clinical sites
  - **Patients**
  - Tests and visits

More at:
https://www.cancer.gov/news-events/cancer-currents-blog/2020/covid-19-cancer-nci-response



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Why are these important to patients?

- **Acknowledges higher risk**
- **Greater convenience**
- **We've been asking for these for decades!**

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Cancer patients have different risks

In treatment

Immune-compromised

Certain cancers more than others?

Metastatic

Comorbidities?

Immune system?

Inflammation?

In remission

Long-term effects?

Comorbidities?

Immune system?

- https://www.vox.com/2020/3/20/21186681/coronavirus-cancer-treatment
- https://www.oncnursingnews.com/web-exclusives/cancer-treatment-during-covid19-pandemic-a-patientbypatient-basis

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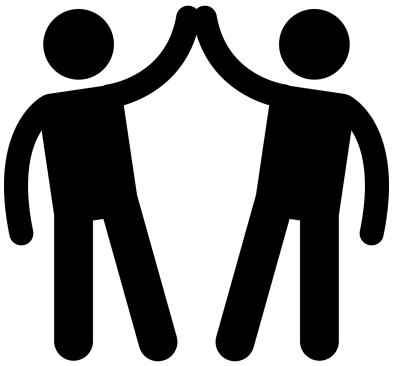
Trial improvements that impact patients

- **Telehealth** & virtual visits
  - eConsent + pre-treatment
  - Follow-up + monitoring
  - Routine checks + support
- **Local** procedures
  - Tests, labs, scans
- Home **shipments**
  - Home care (sometimes)
- **Technology** & devices
  - WIIFP: data + what for patients?
  - Capture missing data



We want these improvements to stick AFTER COVID-19!

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Momentum building…

How do we capitalize on this?

CLINICAL LEADER

Trial Design | Partnering | Clinical Technologies | Regulatory | Market Research | Find A Partner | Clinical

From The Editor | April 23, 2020

Post COVID-19: Clinical Trials Will Never Be The Same

By Ed Miseta, Chief Editor, Clinical Leader
Follow Me On Twitter @EdClinical

NIH NATIONAL CANCER INSTITUTE

1-800-4-CANCER Live

Responding to Coronavirus, Cancer Researchers Reimagine Clinical Trials

"We've learned some lessons," said William Dahut, M.D., who is scientific director for clinical research at NCI's Center for Cancer Research and conducts clinical trials. "My hope is that we emerge from this period with improvements in the way we conduct cancer clinical trials."

s are also contacting IRBs for guidance on

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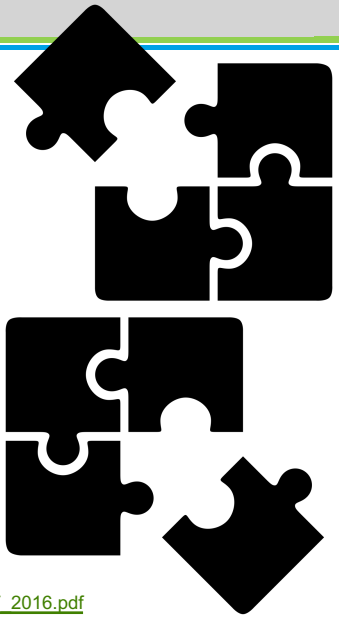
We also want permanent changes in…



Adaptive design in protocols (since 1969)
- Learn as we go, pre-determined
- Rules to analyze, stop, etc.

Platform trials
- More chances for newer approaches

Patient-relevant **endpoints**
- Including PROs and patient experience

Broader **eligibility**
- FDA-endorsed: Age, comorbidities, HIV, brain mets

Crossover/treatment switching
- http://www.cmtpnet.org/docs/resources/Treatment_Switching_Guidance_Document_OCT_2016.pdf

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I have a dream… you can help!

Create future clinical trials + products that meet patient needs

ANALYZE EXISTING TRIALS
What can we do better?

WHAT PATIENT QUESTIONS COULD BE ANSWERED?
Learn from real world use

INCORPORATE LESSONS INTO NEW TRIALS
e.g. design, endpoints, eligibility, PD, PROs, biomarkers

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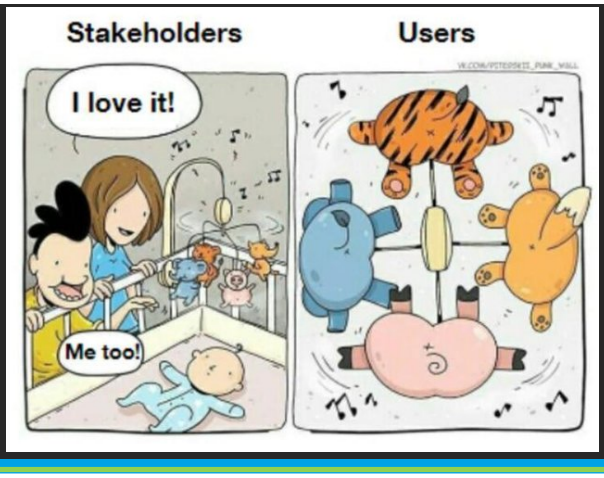
Context…

One final point



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Your thoughts?

- eConsent FDA info: https://www.fda.gov/media/116850/download
  - At a minimum, patients can get a .pdf sent to them by mail or email, discussion through telehealth (at least phone) and then sign, scan/email or mail back.
  - Some sponsors have full eConsent now w/video, explanations, way to record patient understanding (e.g., questions to answer), and then electronic signature.

  Issue getting copy while help a patient:
  - Sites deciding what can/can/t be done.
  - Should be able to get a copy of protocol and consent form. Some sites don't practice HIPAA as intended and make it a barrier.
    - Patient should be able to designate you as ok (may have to sign another HIPAA authorization?)
    - As PA, it's important to ask why, explain it doesn't happen elsewhere, and what can be done to change this?
- Telemedicine: FDA info: https://www.fda.gov/media/109521/download
  - Concerned if insurance will continue to cover in future
  - Also issues with limited internet access (rural, some urban, etc.)
    - We may need to work with/support other systemic initiatives like expanded broadband services, etc.
    - A lot of telehealth calls have been set up with phones for video calls, etc. but can still be a problem in some remote areas.

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Your thoughts + resources

- Eligibility expansion for cancer clinical trials
  - FDA and collaborators (ASCO & FOCR) have put together information on it:
    - https://www.fda.gov/media/110332/download
    - 2017 article from ASCO & FOCR: sent separately
    - Age (12y+), comorbidities (kidney, liver, cardiac, prior/concurrent malignancies), HIV, brain mets (stable)
  - 2020 plan: expand eligibility categories to include
    - Washout periods, concomitant medications, prior therapies, laboratory ranges & test intervals, and performance status
  - Frustrating to hear clinicians assume it's because patients don't understand
    - Often, the criteria are so restrictive it's very difficult to get into trials, especially for very sick cancer patients.
- Also info on diversity is being updated
  - https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enhancing-diversity-clinical-trial-populations-eligibility-criteria-enrollment-practices-and-trial
- And FDA Patient-Focused Drug Development plans
  - https://www.fda.gov/about-fda/oncology-center-excellence/patient-focused-drug-development

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Patient Advocates In Research (PAIR)

Where research meets reality

Thank you! Keep in touch

Deborah Collyar

deborah@tumortime.com

https://collyar.wordpress.com/

www.linkedin.com/in/deborahcollyar/

@deborahcollyar

www.facebook.com/DeborahCollyarAuthor

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