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Rush University Medical Center

Clinical Cancer Research During the COVID 19 Pandemic

Mia Levy, MD, PhD
Director, Rush University Cancer Center

Disclosures

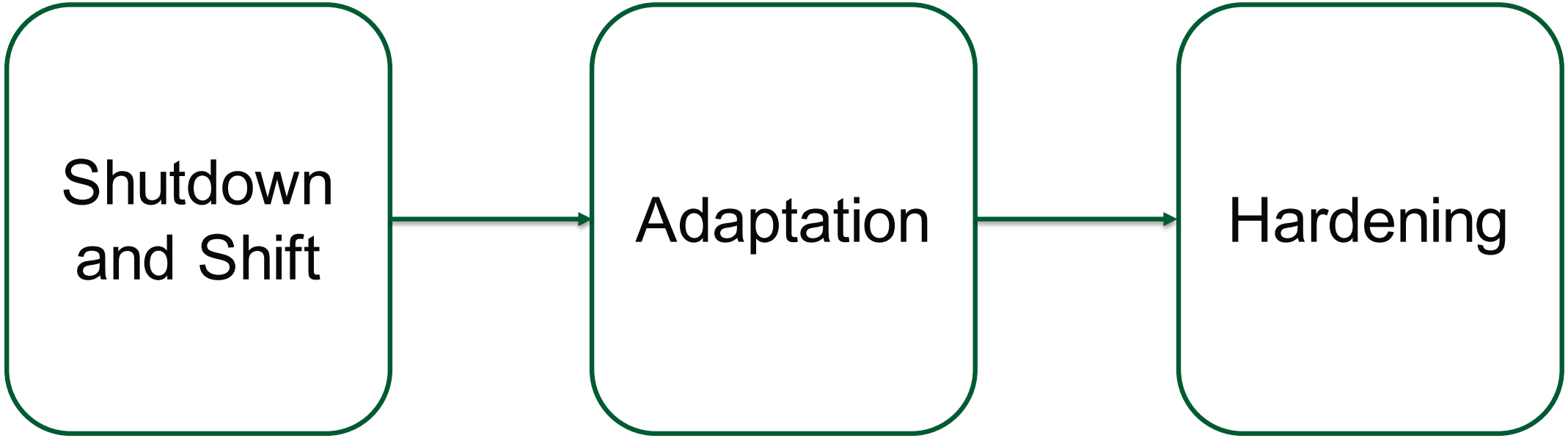
- **Research funding:** Pfizer, BMS, GenomOncology, Komen, NIH/NCI
- **Consulting/Advisory:** GenomOncology, Personalis, Roche
- **Equity:** GenomOncology, Personalis

National Human Genome Research Institute

Cancer Cells Don’t Shelter in Place

Cancer care and clinical cancer research
are essential life-saving services

Phases of pandemic with respect to clinical research process change



Shutdown and Shift: Clinical services

- In-person clinical services shifted to virtual visits
- Diagnostic and procedural services prioritized emergency cases only (diagnostic imaging & cardiology, surgery)
- Lack of access to ancillary services created safety concerns for clinical trial patients on active treatment

Shutdown and Shift: Staffing

Clinical and research staff reallocated to other roles

Lab research staff	→	Develop & run in-house COVID tests
Research nurses	→	Backfill clinical roles, answering hotlines, scheduling
Research coordinators	→	Support new COVID therapeutic studies

Shutdown and Shift

- **Start-up activities:**
  - Many cancer clinical trial start-up activities were paused
  - Focused shift to rapidly opening COVID-19 related studies
- **New accruals:**
  - Slowed but never stopped
  - Prioritized therapeutic cancer accruals where trial was best treatment option for a patient who lacked remaining standard of care options

Adaptation

- **Clinical trial related diagnostic procedures**
  - Initial study deviations
  - Send patient to ED to get study scans for patient safety
  - Rapid COVID testing availability allowed some clinical trial screening and follow-up procedures to resume if pre-tested (imaging, cardiology)
  - Shift from central labs to local labs

Adaptation: In-person activities converted to virtual activities

Informed Consent	→	Electronic Consent
Visits to receive oral investigational drug	→	Mail study drug directly to patient's home
Assessments of patient safety and study adherence	→	Virtual visit

Adaptation

- **Clinical research assessments via virtual visits**
  - Challenges with ever shifting technology requirements
  - Study coordinators did “drive-by” assessments of patients who didn’t have access to technology (patients already on-study)
  - New accruals: technology access became part of screening for potential eligibility
  - Disparities in access to clinical trials when patients did not have access to a compatible devise

Adaptation

- **IRB activities:**
  - Regulations state that any changes to study procedures require IRB amendment
  - 100's of study amendments submitted by local investigators (and later by sponsors)
  - 6-months after start of pandemic, FDA published policy not requiring IRB approval for COVID related study process changes

Hardening: Ongoing work

Virtual Study Audits

- Require a lot of preparation
- Many different technology platforms were tried
- Challenge: need Business Associates Agreement (BAA) with each vendor to share HIPPA protected data
- Industry has not yet settled on best practices or optimal technology workflows

Technologies:

FedX shipping hard drive
Secured email
EPIC Carelink (2 year limit)
RedCAP
Dropbox
Microsoft Teams
VevvaSiteVault

New Challenges

The Great Resignation of 2021

Clinical research staff are leaving medical centers at staggering rates

- Salary competition with industry
- Inability to rehire
- Mandatory vaccinations at medical centers

Lesson learned from ultra rapid activation of COVID-19 therapeutic studies

- Full therapeutic interventional COVID studies activated in 7-10 days
- Near realtime IRB approval:
  - IRB meeting 2-3 times per week including weekends
  - Reviewers meeting 2-3 times per week including weekends
  - Sponsors were just as responsive

"If we are all collaborating and working in real time and don't stress over minor language details, we can get a lot of studies opened quickly. The goal was to get the study opened quickly to hopefully save lives and not everyone covering their butt."

Summary

- We can accomplish a great deal quickly when we all are rowing in the same direction
- Rapid change is possible in clinical research
  - *Historically slow due to heavy regulation*
- Study start-up sprints between local institution and sponsor are highly effective for rapid study activation
  - *How can we replicate this process?*
- Clinical research workforce challenges were difficult pre-pandemic and are in a crisis today

Thank you.

mia_levy@rush.edu

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