# Not by Choice, But by Necessity: An Institutional Response to Research and the Pandemic

Clinical Trials Ontario

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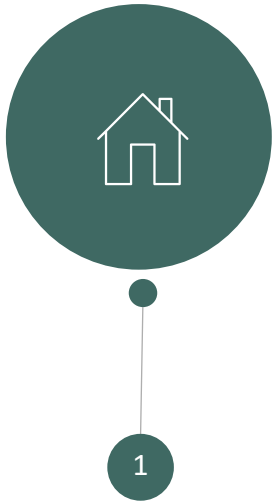
# In the Beginning

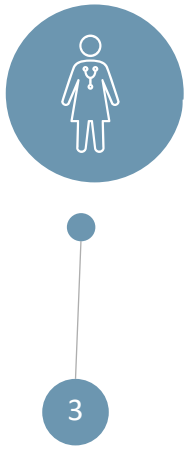


1

Promote maximum patient and staff safety, reduce COVID exposure risk by limiting those on campus

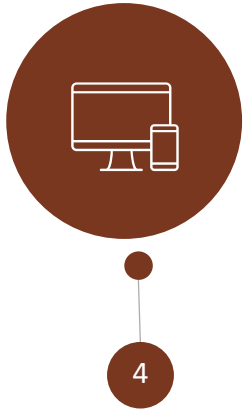
2

Focus on core business



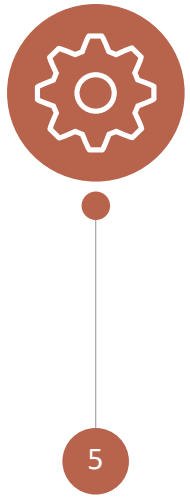
3

Scale back clinical activity, particularly ambulatory/elective/non-urgent activity, Reduce on-site volumes to open capacity for influx of pandemic patients



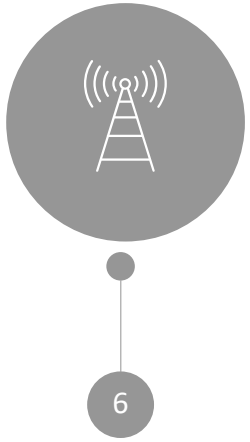
4

Consistent with organizational evolving practices, consider alternative communication avenues with participants/patients – phone, video, email etc.



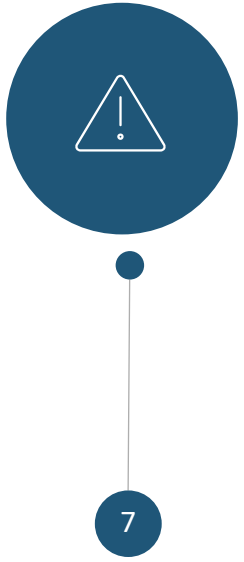
5

Free up human resources for redeployment, Prepare to cross train and/or redeploy staff (i.e., research, finance etc.) to other organizational needs and/or work remotely



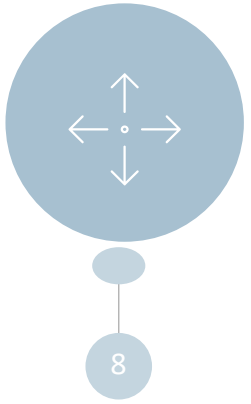
6

Remote work guidance – IT, security, privacy, phone security, platform access, hardware availability, files (physical/virtual), network security, prioritize work/shutter work



7

Prepare for high volumes and staff shortages. Manage PPE, prepare Triage processes/capacity, supply chain, communication plan (internal/external), Command/Control



8

Find agile ways to support rapid deployment of COVID related research

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# As we Stabilized

**1**

Development and implementation of a phased organizational and service re-opening plan, consistent with PH, local and MoH /OH / OHA guidance

**2**

Began to re-engage ambulatory services and visits, prepare for increase in ambulatory visits

**3**

Aling re-opening with organizational priorities, and only as necessary and consistently across organization, according to organizational priorities, monitor indicators (local trends, staffing, PPE, supply chain, PHO etc.)

**4**

Be prepared to reduce volume/activity at any point

**5**

Continue to offer alternative care delivery methods (video/phone/email)

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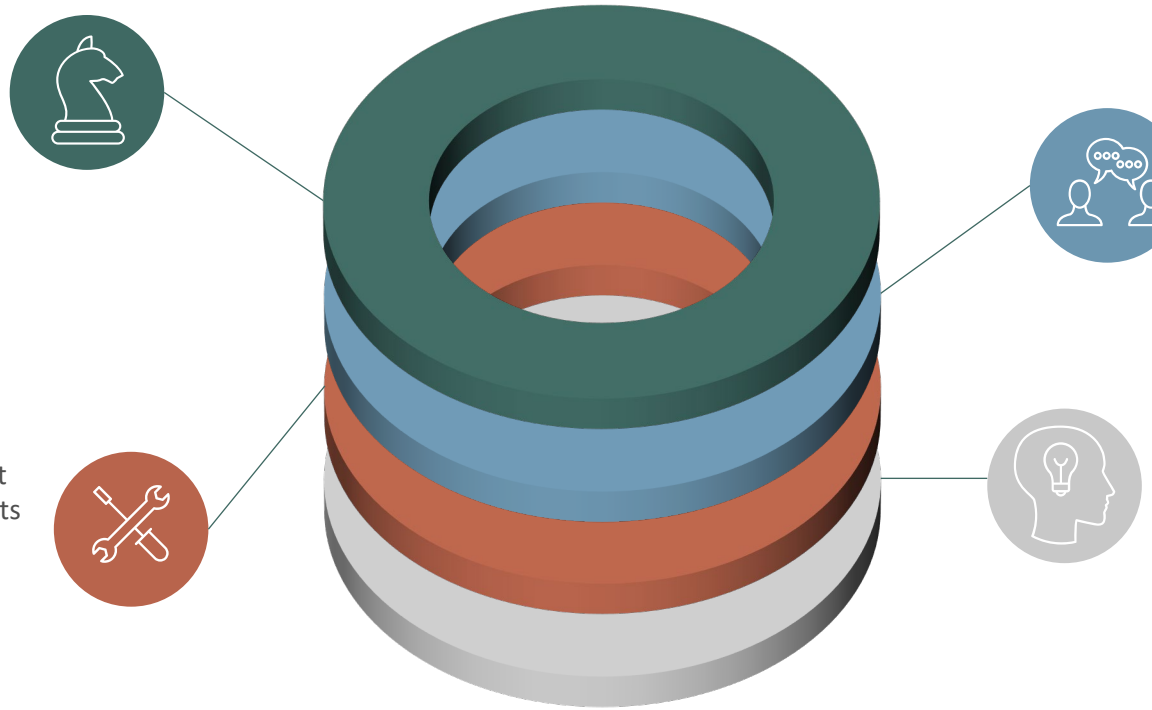
# Dawn of the New Normal

Health care sector recognition that the horse is now well out of the barn (new service delivery / care delivery models/expectations) -
No retreat



Interface of long known consumer demand for more flexible health care delivery models, structures, process and recent lived experience with COVID has driven base state expectations – No retreat

On the research front, adoption out of necessity of many of the elements of “Decentralized Clinical Trials” (DCTs) has occurred, not by choice buy by necessity during the initial COVID era

Research specific impacts - Desire by patients/participants, industry and many PI’s and teams along with HC and others to modernize the approach to trials found its burning platform. Strategic opportunity for change/evolution

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# Moving Forward – Health Sector Realizations

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- Digital and technological solutions have catapulted forward (Digitization is a model, not a technology construct)
  - A range of ambulatory services have and will move to virtual
  - Remote monitoring has and will continue to be propelled forward
  - Quality, data, platforms, security, privacy, identity, user experience, interoperability, AI/ML, business cases, national standards/regulation will be critical
- Moving ambulatory care and care not required in an acute care setting to the community must evolve
- Care at home - Home and community based care and mechanisms to support have been pushed forward by several years, Hospital at Home, Medical Home/Neighbourhood for more acute
- Care delivery models are changing, within and outside traditional institutions (preventative, acute, post-acute, chronic, end of life), social care
- Volume to Outcome / Quadruple Aim (pop health, patient experience, provider experience, cost)
- Primary Care reform more critical than ever, including expansion of potential providers (NP's, non-traditional, psychologists, pharmacists etc.), team based, infrastructure, reimbursement models, data systems
- Health Equity and the Social Determinants of Health have once again, this time more prominently been shown to matter
- The need for health care and public health preparedness
- Provider/patient relationships have and will continue to change
- Patient as consumer has an unrelenting momentum
- User experience is the new normal
- Low Rules environments must continue
- HHR / workforce planning, licensure rules must evolve
- Reimbursement models must mature > pay for outcomes

# DCTs to the Rescue

Trials executed through telemedicine, mobile/local healthcare providers (HCPs) and/or mobile technologies

Measurements can be more frequent or even continuous because they are not restricted by scheduled clinic visits

May use eRecrutiment, eConsent, remote data capture, eCRFs, Direct to Participant Investigational Product, Risk Based Monitoring

A decentralized approach allows trial participants to take part in clinical research from anywhere, with research activities better integrated into their daily routine

Are not bound by the geographic limitations that affect traditional trials

DCT approaches may lessen participant burden (e.g., travel costs and time loss), which may enhance retention and facilitate certain research that may otherwise be unduly burdensome under traditional clinical trial constructs.

Can recruit participants from anywhere, potentially resulting in accelerated enrollment and more diverse participants' representative of the target population

And may be hybrid (using DCT elements and bricks and mortar visits in combination) or purely fully remote DCT.

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Reference - Internet/Broadband Fact Sheet. Pew Research Center

# Institutional Angst

1. Relationship of Research to Core business (community versus academic hospitals)
2. Staffing – employment, liability, insurance, performance, financial impacts, safety onsite/offsite/participants home (mobile HCPs as institution providers)
    1. Staffing – Mobile HCPs - contract/community staff, third party vendors, contracts, legal, licensure, union issues for home visits, training, oversight and liability
3. External Labs/Imaging and relationship to hospital/clinical care – secondary/incidental findings
    1. Clinical care/routine care vs. clinical trial activities – secondary findings, adverse events
4. DCT – 3rd party vendors, turn key services – impacts on current hospital based paradigm
5. Physician/Provider licensure/regulator/reimbursement (Reimbursement for digital/remote etc.)
6. Provincial / Federal legislative framework(s). Geographical jurisdictional issues, compliance with HC, FDA , HCP regulatory
7. CTA's, trial agreements, indemnity and insurance issues, reimbursement model, budgets, additional complexity/costs
8. Equity
9. IMP and role of hospital pharmacy, legislation, regulatory colleges, dispensing, in-house pharmacy or 3rd party pharmacy and delivery/accountability system
10. Governance and Risk Management
11. Changing norms/culture – playbooks, change management, best practices, changed operating models, pain points, impacts on cost/revenue models, traditional/hybrid/pure DCT, KPI's
12. Legal, Liability and Insurance (remote staff, in-home visits by staff/contractors, privacy/breaches), adverse events, process issues (eRecruitment, eConsent – understanding, identity validation)
13. IT/Privacy/Security
    1. Staff use of platforms/systems, digital/remote technologies (apps, wearables, RMT services), bandwidth, cloud, on-prem, system access/capabilities, remote (work from home) or participants home
    2. Use of AI/ML components
    3. Participants – access to, use of, support/training needs
    4. Storage of digital information, PHI, PI, PROMs Real World Data (RWD)
    5. Technologies – reliability, quality, security, privacy, use of pre-existing platform/technology versus adding new, existing/new 3rd party vendors, costs
    6. Data integrity/quality/interoperability, (RWD) interfaces with EMR, existing platforms/technology, data >verification, validation, usability
    7. Financial considerations related to IT/Privacy/Security, data integrity, additional storage costs, technology support/training
14. REB capability, expertise, span of control, alignment of organizational polices, Research SOPs, RHPA regulations, PHIPA, additional organizational burden
15. Safety Monitoring – lead / satellite site >accountabilities/responsibilities, legal, liability, insurance, quality, qualifications, monitoring, training
16. Traditional trials > DCTs, > In Silico trials (computational models to simulate how a drug, medical device, or intervention will affect a virtual population) (radiology/phantoms)

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