



Developing and Maintaining an Alternative Business Process During an Ever-Changing Global Pandemic

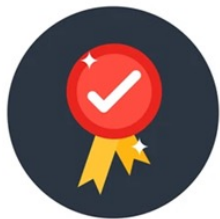
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Outline

- Pandemic impact on randomization schedule distribution
- Implementing an alternative process
- Maintaining the process in an ever-changing environment
- Learning from our experiences

Process and Impact



Tried and True

Long standing process



Confidential

Require robust controls



Manual

Physical paper delivery



Halted

Unable to deliver information

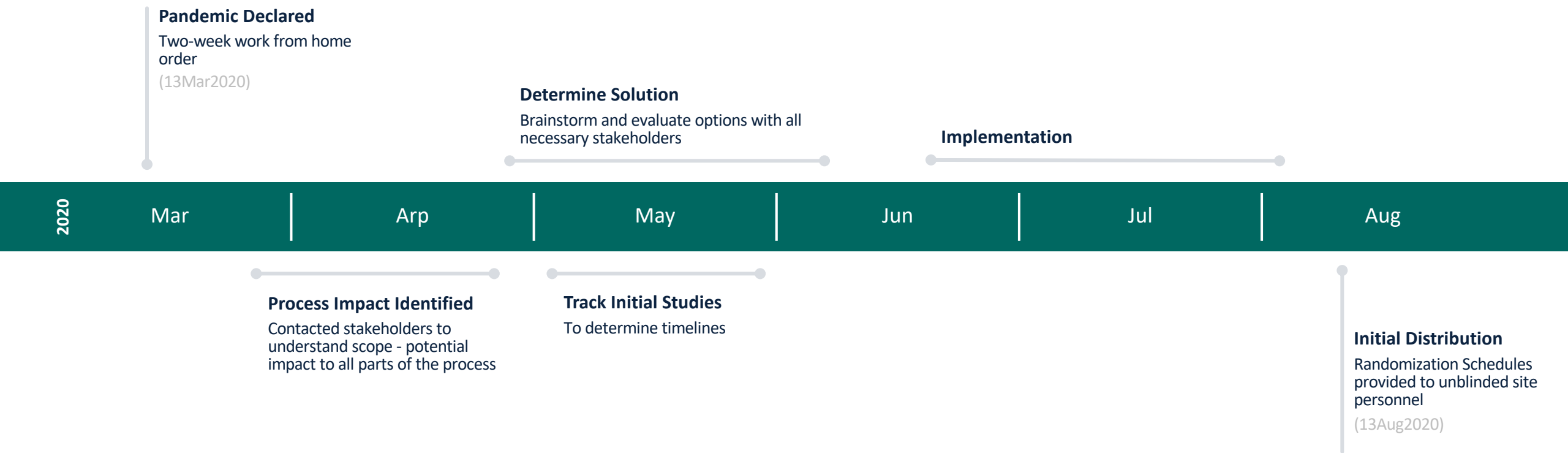


Risk

Delay clinical study initiation

Implementing an Alternative Process

Process Timeline



Determine Solution

Involve all necessary
stakeholders - including
Compliance

Considerations

Risks

Compliance

Feasibility

Impacts

Resources

Timelines

Implementation

Documentation	Communication	Training	Monitoring
SOP exception log Alternative procedures SOP Reference documents (alternative versions)	Internal External Email templates	Internal audience – process Functional area specific External audience – technology	Solicited feedback Periodic evaluations Adjust as necessary
Functional area SMEs			

Maintaining the process



Time Marches On

Never expected to sustain process for so long

Revisions/updates to process as situations changed

Alternatives to the alternatives

External Users

Set-up Time

User Knowledge

Technology Capabilities

Resource Intensive

CHALLENGES

Learning from our experiences

What have we learned?

Technology has advantages but...

...not always the easiest approach

...has limitations



Where are we now?

Piloting a new permanent process...

...opportunity to modernize the process in our digital age

...simplified, long-term, universal, secure



Wait and see...



Thank you

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