IIT Toolkit

26th April 2021

MACH Snr Project Officers:
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VICTORIAN COMPREHENSIVE CANCER CENTRE

MACH Melbourne Academic Centre for Health

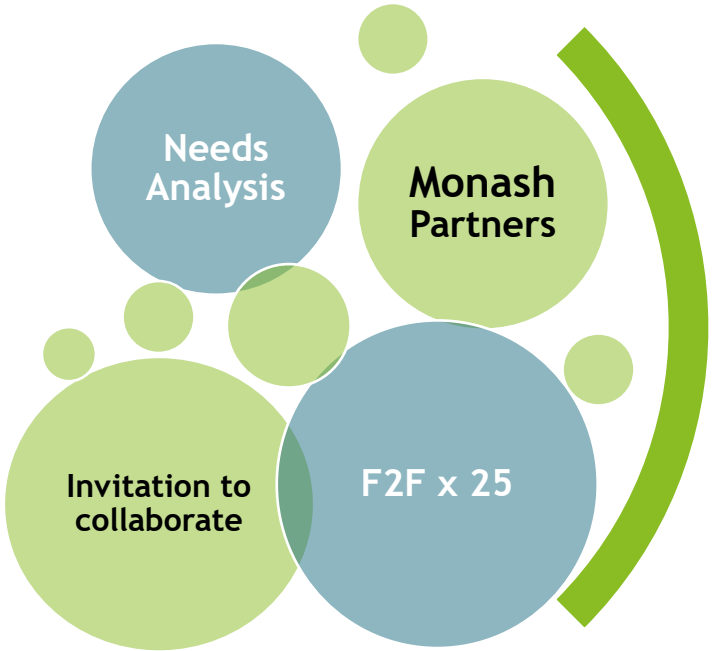
murdoch children's research institute

Who is MACH Melbourne Academic Centre for Health ?

- Australian Health Research Translation Centre
- 19 research partners
- Identifies gaps in the Australian healthcare and health research systems
- Identifies priority areas
- Guides collaborative research programs

The Steps

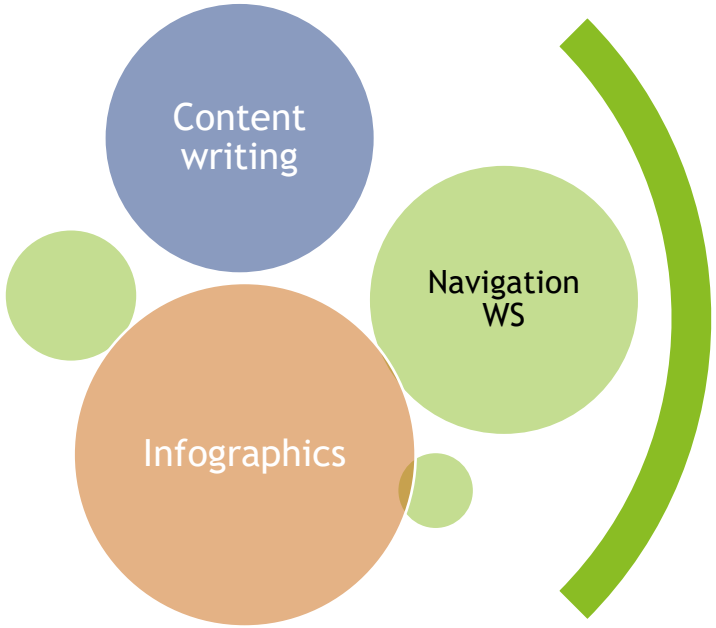
1



MEET & GREET

Steps Cont’d

4



Website Development

What?

- Supporting Content
- Guiding principles
- Covers all stages of trial life cycle
- Reflect current applicable regulatory requirements
- User friendly

Resources

- Guidelines
- SOPs
- Templates
- infographics

- Monitoring Safety
- Monitoring Trial Conduct
- Risk Management
- Data Management
- Budgets
- Feasibility
- Clinical Trial Lifecycle
- Roles and Responsibilities
- Resources
- Glossary of Terms

How?

1. Download
2. Tailor
3. Give credit

Resources

46 Resources:

10 Templates

5 Operating Procedures (SOPs)

12 Guides/Plans

6 Process Flow Diagrams

13 Explanatory Infographics

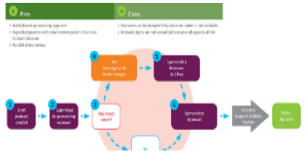
Clinical Trials Data Management Life Cycle

This infographic is a useful tool to assist Investigators to understand the data management processes that occur throughout the life cycle of a clinical trial.

Data management tasks begin during the protocol development phase and occur throughout all stages of the trial from clinical trial planning, through trial conduct/data verification/analysis, dissemination of results, and into the future with options for data sharing.

Trial close-out | Data management | Trial planning | Trial conduct

VIEW ASSET



Level 1 Sponsorship with No Committee

This approach provides a high-level overview of the processes an organisation can implement in order to provide a minimum level of assurance and adequate risk assessment for investigator-initiated trials.

The Principal Investigator applying for institutional sponsorship submits their application, including their draft protocol, to the institution's Research Office. Depending on the institution, the application for sponsorship may be approved before the Investigator can submit an application for ethical and/or governance review, or alternatively, ethics review may occur in parallel with sponsorship review.

Risk | Sponsorship | Trial planning | Trial conduct

GO TO SOURCE

Risk Impact Assessment Matrix

The Risk Impact Assessment Matrix can be used to assign an impact rating (low, medium, high) to individual risks identified for a trial.

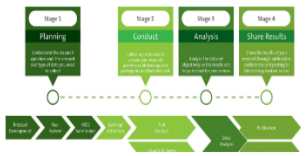
The matrix uses the consequence of the risk (insignificant, minor, moderate, major, catastrophic) and the likelihood of it occurring, to assign the risk impact. Any risks considered to have medium or high impact should have a mitigation and management plan.

Risk | Sponsorship | Trial planning | Trial conduct

GO TO SOURCE

Level 2 Sponsorship Process with Committee

This approach uses a Sponsorship Committee to approve requests for institutional sponsorship of investigator-initiated trials. If the host institution/organisation conducts high risk trials, it may be appropriate that the institution's sponsorship approval process include a sponsorship committee to provide an appropriate level of assurance and adequate risk assessment.



Life Cycle of a Clinical Trial

The Sponsor-Investigator and clinical trial team, including co-investigators, study coordinators, research nurses, trial pharmacists and other supporting department staff, have responsibilities for the delivery of clinical trials that generate high-quality data in a safe environment.

It is useful to understand these responsibilities in terms of the four main stages of a clinical trial: planning and design, conduct, data analysis and dissemination of

Institutional Sponsorship and Approval of Investigator-Initiated Trials SOP

Describes a risk-based approach organisations may use to determine if they are willing to sponsor an investigator-initiated trial. Successful applications will be issued with a Certificate of Sponsorship (signed by a representative of the committee and the Sponsor-Investigator) that outlines the tasks that the sponsoring institution has delegated to the Sponsor-Investigator as a

IIT Toolkit Utilisation

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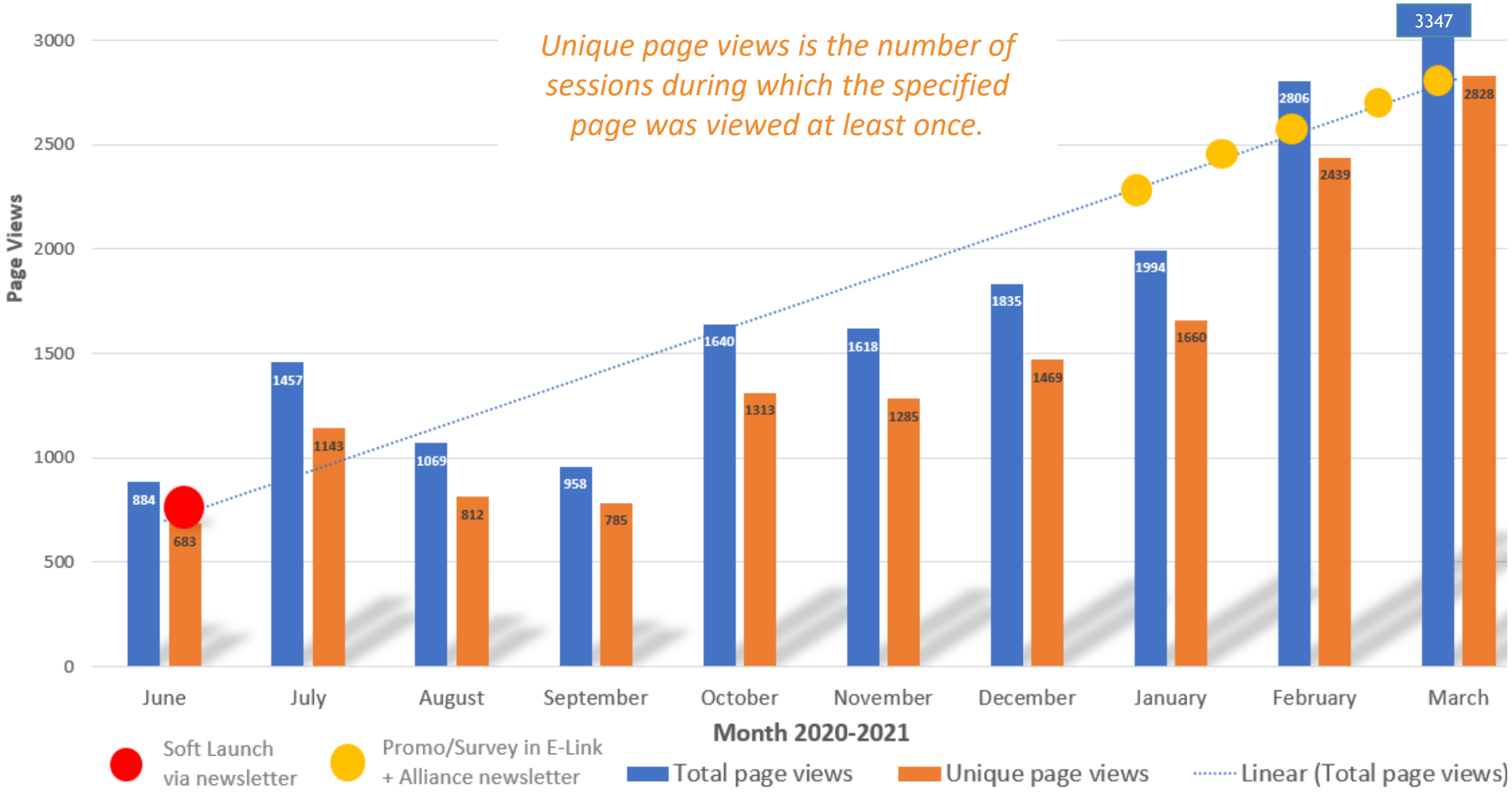
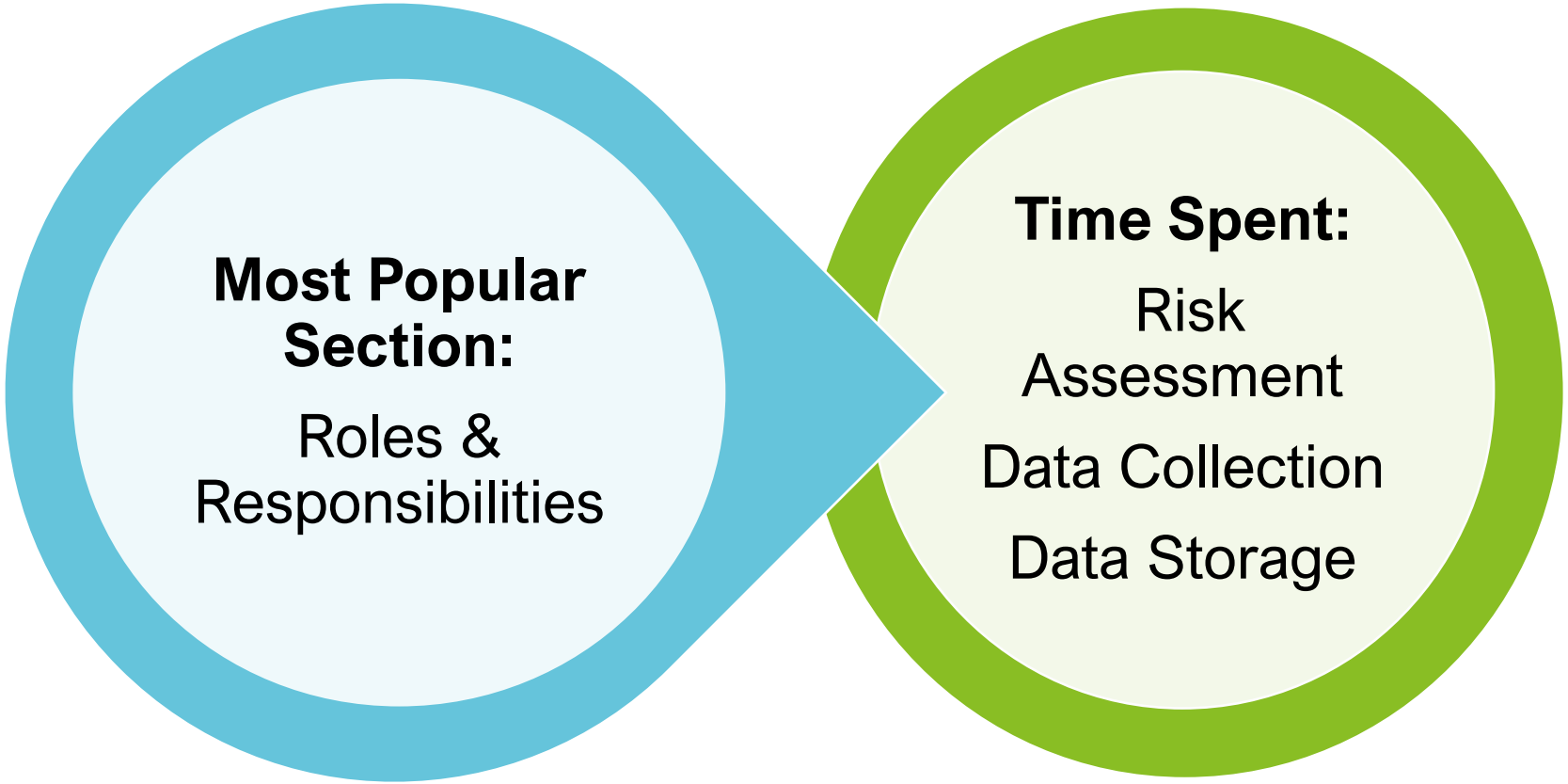
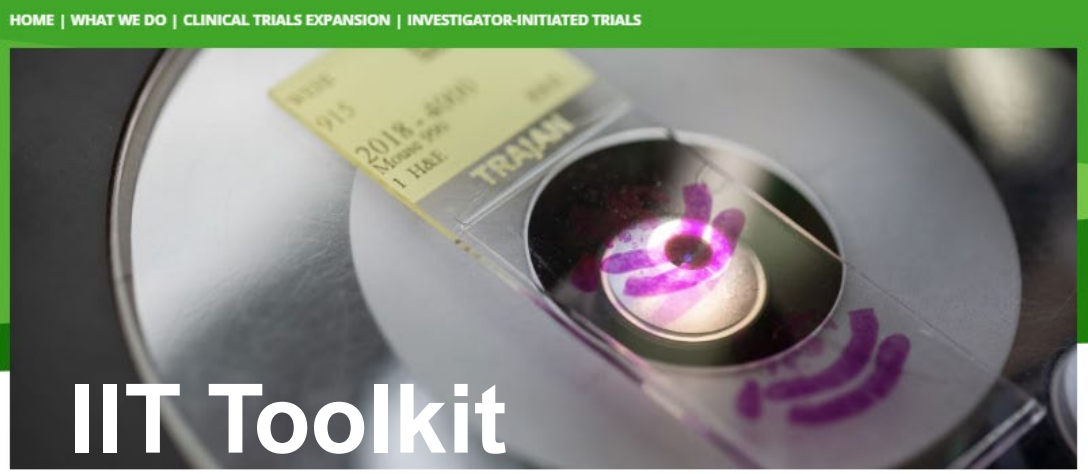


IIT Toolkit Utilisation





CLINICAL TRIALS EXPANSION

- Registry Trials
- **Investigator-Initiated Trials**
  - Data Management
  - Monitoring
  - Risk Management
  - Resources
  - Support Mechanisms
  - Glossary
- Teletrials
- Building Capability
- Workforce
- SiteDocs
- Adolescents and Young Adults

Contact

Toolkit

For information or assistance related to the IIT toolkit
E iit-toolkit@mcri.edu.au

Support Mechanisms

Kate Khamly
VCCC Program Manager

Share

Investigator-Initiated Trials

Clinical trials are commonly led by pharmaceutical and biotechnical organisations, overseen by a panel of experts and implemented through clinical trial units.

Investigator-initiated trials (IITs) are established and managed by non-pharmaceutical researchers, such as clinicians and researchers working in a health institution. Most IITs are designed to support the development of new clinical practice guidelines or compare the effectiveness of existing treatments.

Effective use of existing structures and governance

In Victoria, 70 per cent of all cancer clinical trials are conducted at either Western Health, the Royal Children's Hospital, the Royal Women's Hospital, Peter MacCallum Cancer Centre, St Vincent's Hospital Melbourne or Austin Health - the clinical members of the VCCC.

These institutions provide a critical mass of successful clinical trial facilities and clinician researchers, with proven infrastructure and reinforced governance methods. The investigator-initiated trials approach benefits from the facilities' knowledge and resources; providing a greater variety of trials to a larger pool of patients.

IIT resources for researchers

Melbourne Academic Centre for Health

The VCCC has partnered with the Melbourne Academic Centre for Health (MACH), and with assistance from the Melbourne Children's Trials Centre, to develop a suite of resources to support researchers conducting investigator-initiated trials.

GOOGLE:
Investigator Initiated Trials

https://www.viccompcancerctr.org/what-we-do/clinical-trials-expansion/investigator-initiated-trials/

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THANK-YOU