Australian Government
Cancer Australia

Australian Comprehensive Cancer Network

ACCN Innovations Showcase

Networked Research Programs

A/Prof Craig Underhill

Regional Trials Network-Victoria

Australian Comprehensive Cancer Network

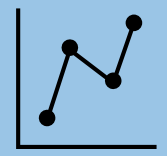
Standards of excellence for networked comprehensive cancer care in Australia

Australian Government
Cancer Australia

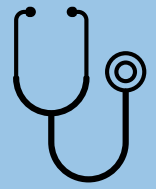
Deliver **comprehensive cancer care**

Deliver **equitable access** to **culturally safe care** across the cancer continuum

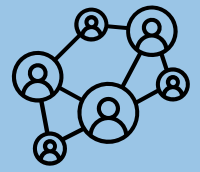
Deliver **research excellence**



Collect, share, and report **comprehensive cancer data** to drive service improvements and better cancer outcomes



Foster an **engaged, capable, and future focused** cancer workforce



Deliver **connectivity and sharing of expertise** across the network

Self-evaluate performance and adherence with the standards of excellence

Who are the National Cancer Cooperative Trial Groups?

x14 national Cancer Cooperative Trial Group (CCTG)

- represent multi-disciplinary member-based organisations
- lead the conduct of multi-site, multi-state, clinical trial research
- Research in areas of disease (different cancer types) or technical expertise (paediatric, radiation, psycho-oncology

Well organized, well governed, volunteer-based organisations

Many benefits to National CCTGs

- Efficiency and speed, with national and international reach
- Include diverse populations, with innovative models to conduct of high impact, high value research eg teletrials, e-consent,
- Advance Australia's position for better science, new diagnostics, treatments
- Retain health and medical researchers in Australia, increase expertise, education and development through mentorship
- Support evidence for new medicines and services
- Consumer representation and engagement with patient groups
- Collegial, shared sense of purpose and pride in advancing better outcomes for patients

ANZCTR

600,000 Australians per year consent to participate in a trial

Industry contributes $930m to the $1.1b spend on CT in Aus

Increase in non-commercial IIT

Decrease in the av sample size

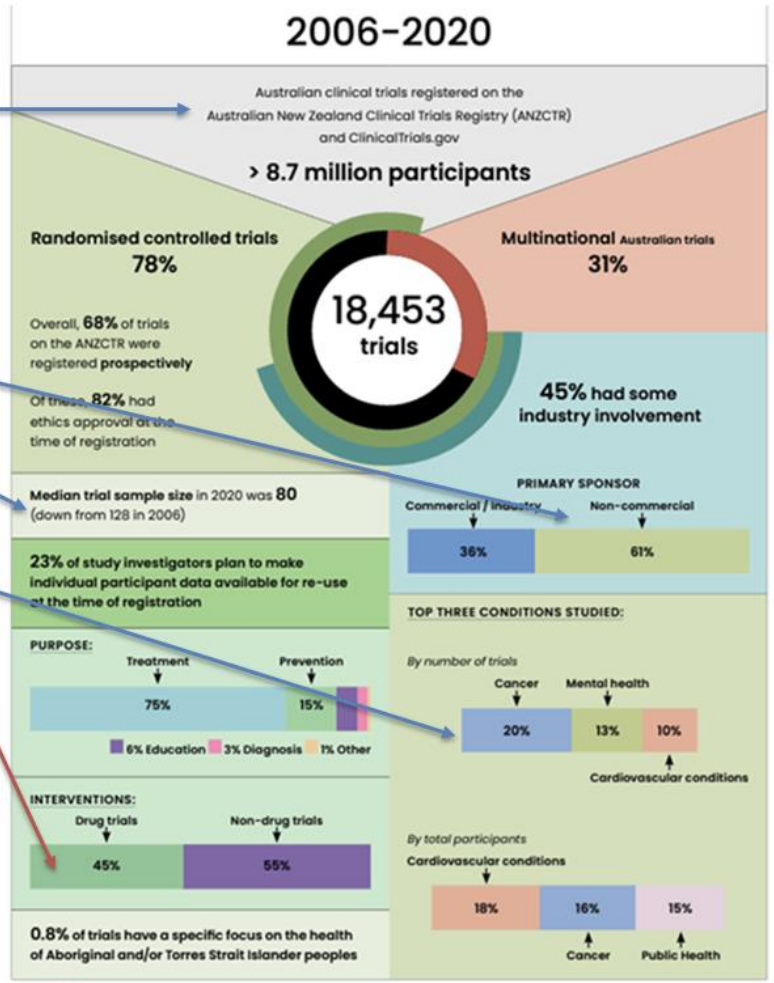
Cancer most studied area – 20% all trials

45% trials =drug treatment intervention

Australia is **a leader in investigator-initiated trials**, where doctors, researchers come together to investigate a critical need in treatments.

$1 = **$5.80**

For each $1 invested in clinician-driven clinical trials in Australia, **benefits of $5.80 can be realised.**



ANZCTR
Australian New Zealand Clinical Trials Registry

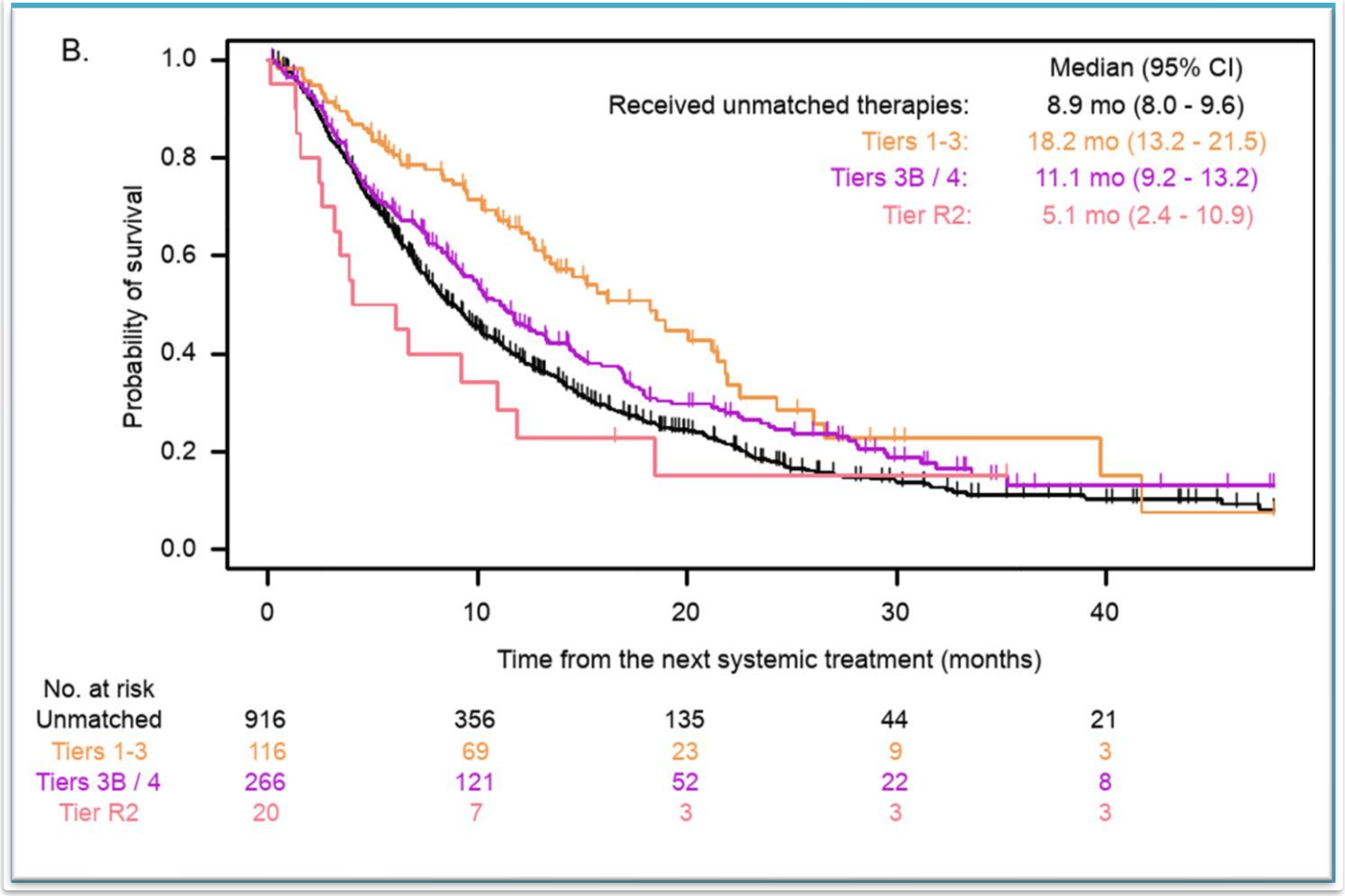
The health of RRR patients

- *On average when compared to people living in metropolitan areas* Australians living in regional, rural and remote areas have:
  - shorter lives
  - higher levels of disease and injury
  - poorer access to and use of health services*
- Face barriers taking part in clinical trials
  - cultural differences
  - geographical isolation.
- Improved survival associated with enrolment on clinical trials *Unger et al 2014*
- Rural and urban patients with equal access to SWOG trials had same survival *Unger et al 2018*

**Commonwealth Australian Institute of Health and Welfare, Rural and Remote Health 2019*

Real world impact: biomarker-targeted therapies

37.5% of patients have a T1-3 biomarker (prospective clinical evidence for benefit)



Frank Lin

Lin et al. Criteria-based curation of a therapy-focused compendium to support treatment recommendations in precision oncology. 2022 *npj Precision Oncology*

prospect.

PrOSPeCT: a $185M initiative

Establishing Australia as a regional hub for cancer drug development and building the digital economy in health analytics.

PrOSPeCT (Precision Oncology Screening Platform enabling Clinical Trials) is an Omico project that will...

1

Provide broad-based access to comprehensive genomic profiling for non-curative solid or haematologic cancer patient populations – **conducting large-scale genomic screening of 23,000 patients**

2

Maximise opportunities in clinical trials by identifying patients for specific biomarker-dependent clinical trials – **driving the efficiency of patient recruitment and decreasing trial costs**

3

Enhance biomarker-dependent drug development by enabling advanced molecular analyses – **creating a real-world dataset and analytics platform with national scale comprising 23,000 patients and more**

PrOSPeCT will be delivered alongside a public-private consortium of partners from across the Australian genomics and clinical trials ecosystem

Major Sponsor*

Australian Government
Department of Industry, Science and Resources

Commercial Collaboration Partners

Roche
Omico.
Children's Cancer Institute
NCI AUSTRALIA

Delivery partners

Peter Mac
SA PATHOLOGY
Garvan Institute of Medical Research
NSW Health Pathology
ATGC Australian Translational Genomics Centre
quantium
illumina
PathWest
NACCHO
Aboriginal Health & Medical Research Council of NSW
SYNERO
SONIC HEALTHCARE
MICROBA
George Clinical
PRAXIS

* Funding from the Australian Government is part of the Modern Manufacturing Strategy

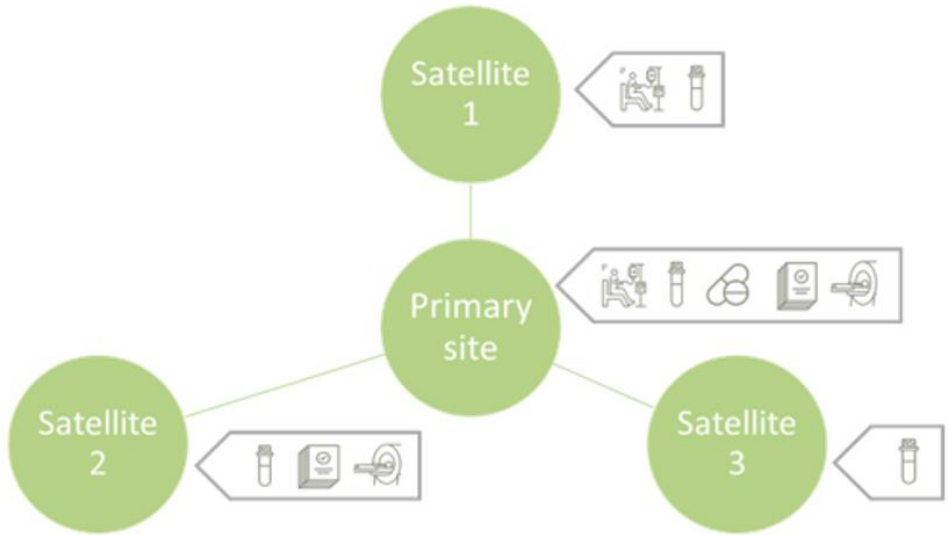
A teletrial is a group of clinical trial sites that work together to conduct a clinical trial under the supervision of a Primary Site.

The Australian Teletrial Program (2022)

Australasian Teletrial Model

Primary site	Tele-health	Satellite site
Specialists	Patients are consented, recruited and managed at satellite sites in partnership between clinicians from satellite and primary sites.	Patients and families
Clinical trial coordinators		Medical officers
Specialist pharmacy, nursing and allied health clinicians		Nursing, pharmacy and allied health clinicians
Administration support officers		With/without trial coordinators
		(Larger centres may have specialist doctors, nurses, pharmacies and allied health clinicians)

Sabesan & Zalcberg, EJCC, 2016



Sabesan S, et al. COSA Australasian Tele-trials Model

Strategies to improve rural clinical trial participation

Special Articles

Check for updates

Improving Rural Clinical Trial Enrollment: Recommendations From the Rural Health Working Group of the Alliance Clinical Trials Network

Nicole L. Stout, DPT, CLT-LANA, FAPTA[1,2]; Daniel Nikcevich, MD, PhD[3]; Tara O. Henderson, MD, MPH[4]; Preston Steen, MD[5]; Matthias Weiss, MD[6]; Steven Ades, MD[7]; Tammie Mlodozyniec, BS, CCRP[8]; Amy Koffarnus, BS, CCRP[9]; Betsy Barnick, MS[10]; and Electra D. Paskett, PhD[11]; on behalf of the Alliance Rural Health Sub-Committee of the Community Oncology Committee members

DOI https://doi.org/10.1200/JCO.23.01667

Strategies to improve rural clinical trial participation

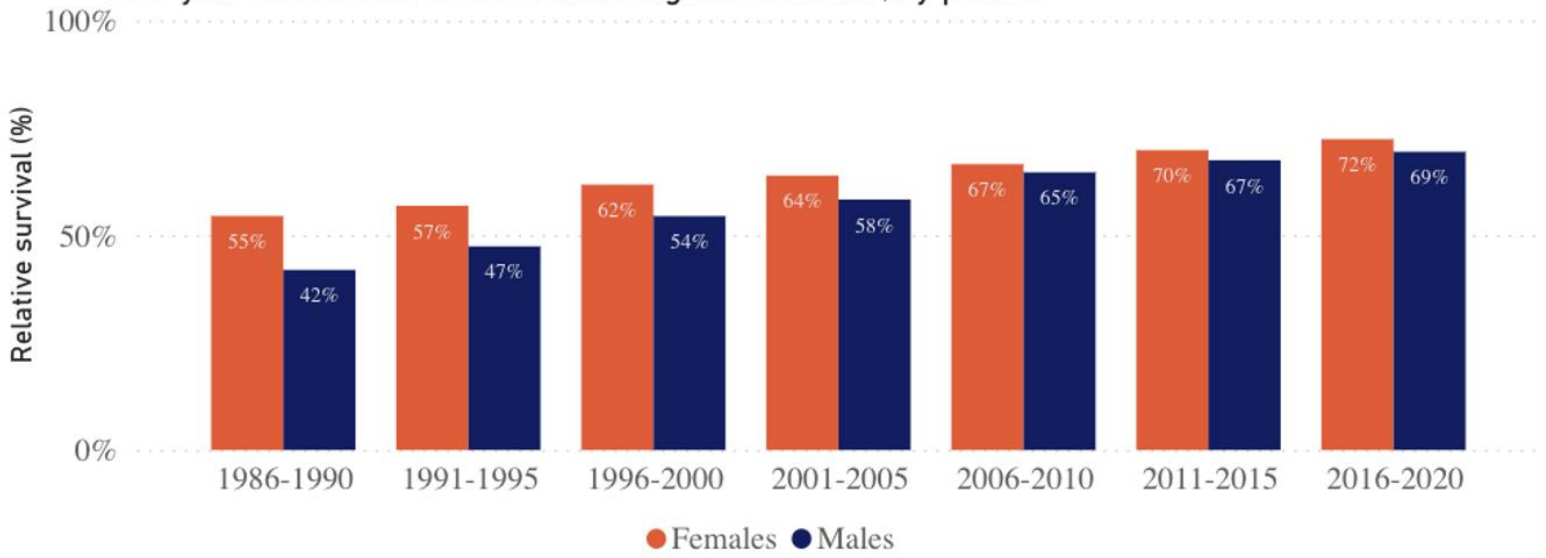
Trial Design Consideration	Methods	Approach
Classify rurality of participants[13]	On the basis of the goals of the study, identify a rural classification coding system to guide target recruitment and/or characterize study participants *RUCC*—County-level classification of rurality on the basis of population and proximity to metropolitan areas *RUCA Codes*—Census tract and zip code classification of rurality on the basis of geographic proximity and commuting flow into and out of urban centers *UIC*—County-level classification on the basis of proximity to nearest metropolitan area *FAR Codes*—Zip code level classification on the basis of travel time by car to nearest urban area Codes can be used to reflect rural residency at the level of the individual, however could also be used to delineate rurality at the clinic site level	Use a classification system to delineate between urban and rural study participants for accrual tracking Consider if an objective of the study is to target enrollment of rural populations and choose a classification system that aligns with the study intent to establish enrollment thresholds eg, >50% of enrollment will be among patients residing in RUCC 4 and above areas
Low burden imaging	Minimize repeated imaging tests within the trial. Use an approach that is least-intrusive as possible Minimize the number of complex imaging tests	Consider partnerships with rural hospitals or health care centers for repeat imaging Identify mobile imaging units, if available, as potential partners Align with NCCN current guidelines for standard of care Consider insurance coverage barriers when exceeding established standards of care Broader window of image eligibility (eg, minimum of 4 weeks) Allow consideration of anatomic imaging (CT) in lieu of functional imaging (PET), when appropriate
Remote consent	Make available to all participants	Continue to allow phone consenting with witness for remote consent Collaboration and training with local health care or community centers/extension offices
Telehealth/mobile technology	Leverage to provide Educational interventions Patient-reported outcomes measures Symptom and toxicity tracking	Consider app-based symptom tracking systems Expanded collaboration with local providers giving access and roles on (decentralized) clinical trial platforms (eg, Commercial Off-the-Shelf platforms like Thread Castor, Clin Capture, built into EHR if available)
Financial support for rural patients	Budget for or collaborate with local foundations to provide transportation incentives to individuals traveling a certain distance to study site Budget for or collaborate with local foundations to provide accommodations for individuals who travel extensively for trial participation	Partner with county or state services for transportation or accommodations needs Budget for transportation incentives, such as gas cards or ride share vouchers per patient The tank of gas is a significant incentive and holds both important practical and symbolic significance
Local care delivery	Identify standard-of-care trial procedures that could be carried out at local clinics or provider offices including Local drug delivery Biospecimen collection Imaging	Provide training to local providers and collaborate on standard drug delivery (eg, delivery of standard of care drug agent could be administered locally [Taxol] without requirement to travel)
Rural recruitment strategies	Consider community advisors from rural health offices Communication with local primary care provider regarding patient eligibility for trial enrollment	Use community events and organizations to socialize clinical trials with the community Conduct informational sessions with local community groups for knowledge and awareness

VCR Data explorer

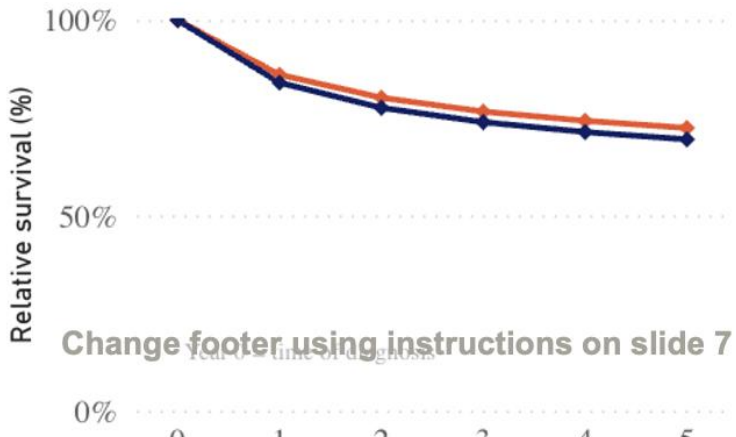
Overview | Diagnoses | Deaths | Survival | About our data

I'm looking at 5 year survival for all malignant tumours in Females Males Persons

Five-year relative survival for all malignant tumours, by period

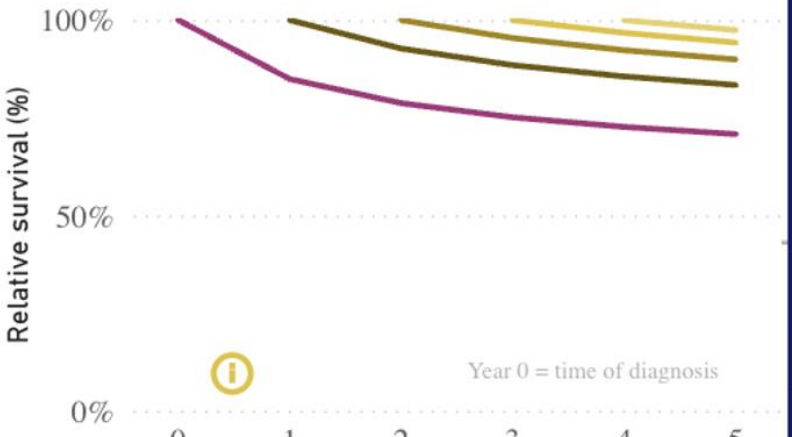


Survival for Victorians diagnosed with all malignant tumours, by year

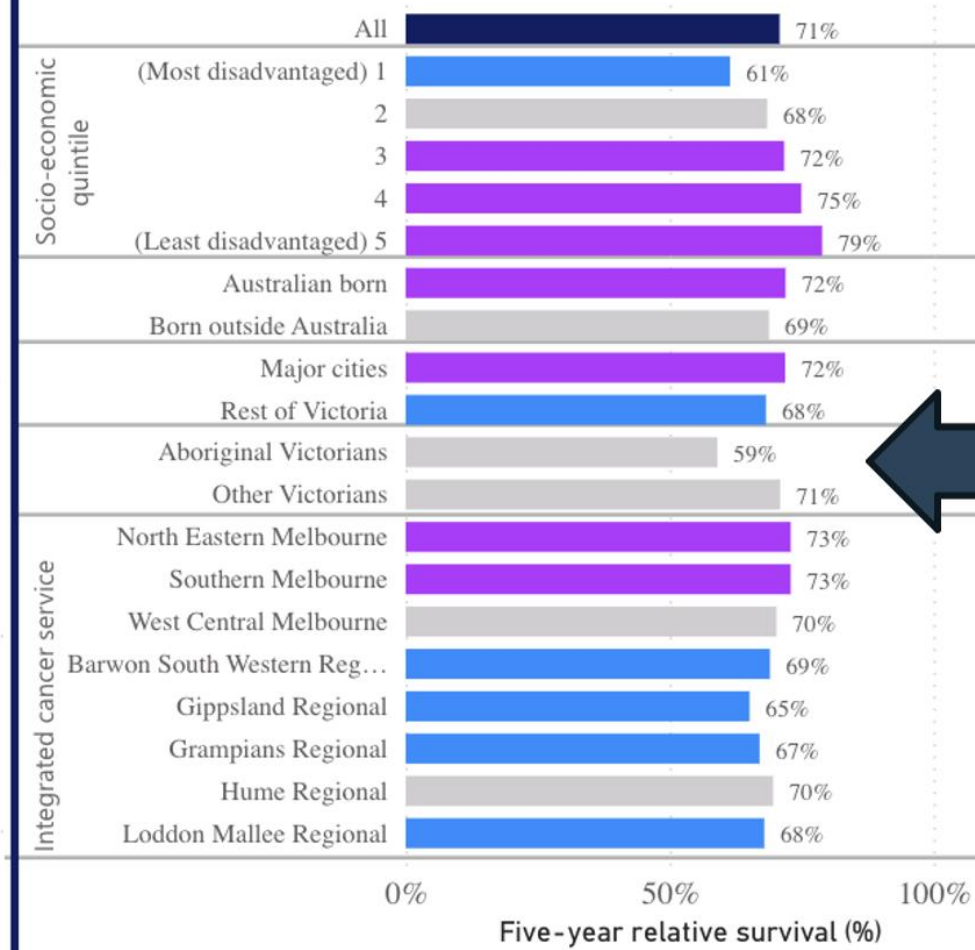


Change footer using instructions on slide 7

Conditional survival by time after diagnosis Victorians diagnosed with all malignant tumours



Variation in five-year relative survival for persons with all malignant tumours for the period 2016-2020

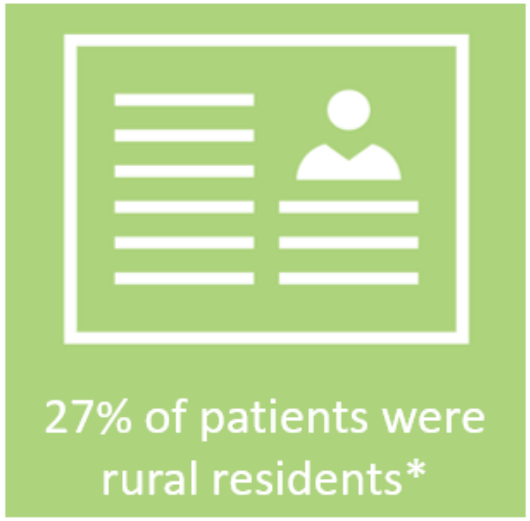


Lower | Similar | Higher

Show disparities for Females Males Persons

Clinical Trials in Victoria 2017:

Cancer Council Victoria Clinical Trials Management System



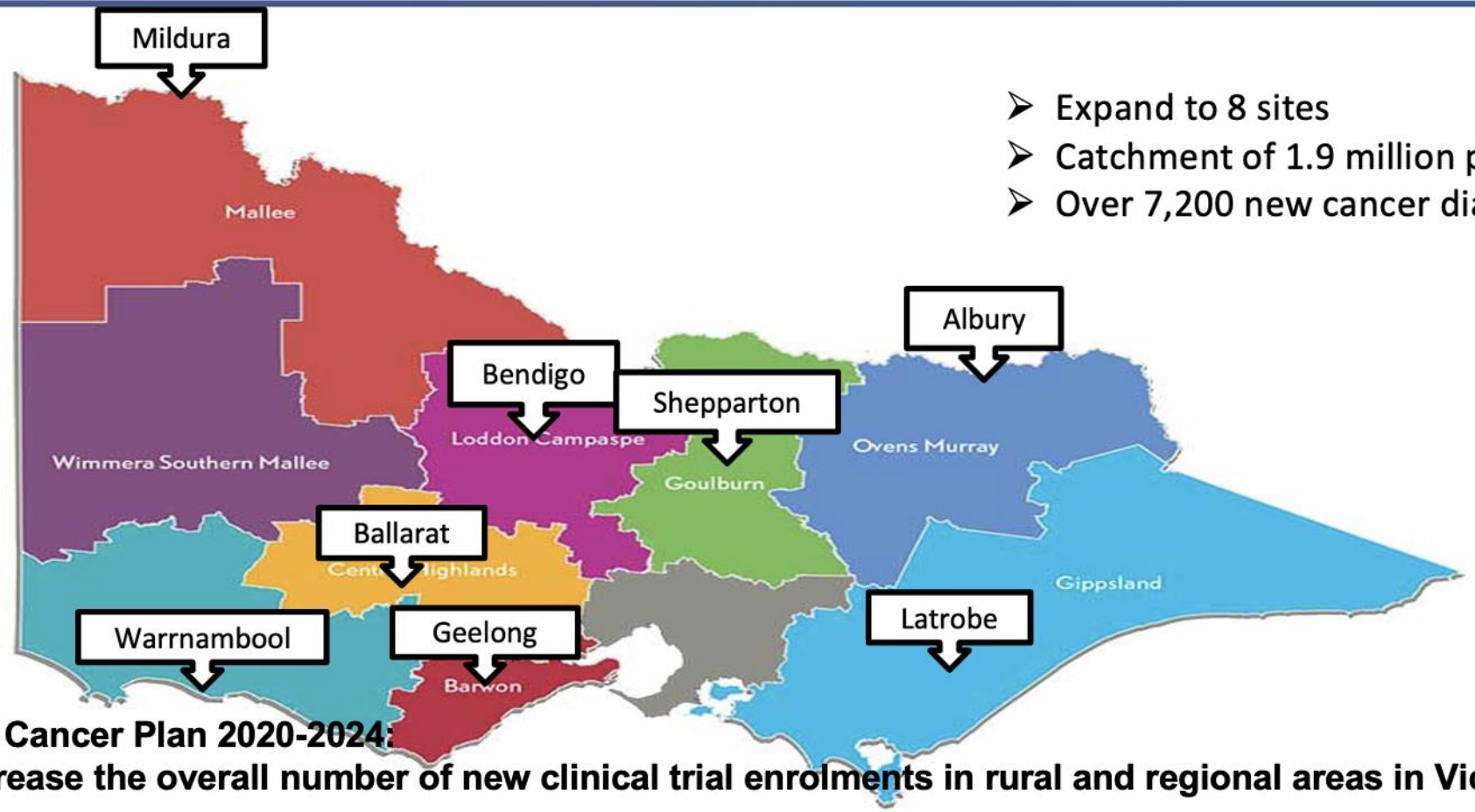
Priority item for Australia: Victorian Cancer Plan 2016-2020

> Address inequitable access to cancer clinical trials for regional patients

** 2017 Cancer Council Victoria, Clinical Trials Management System*

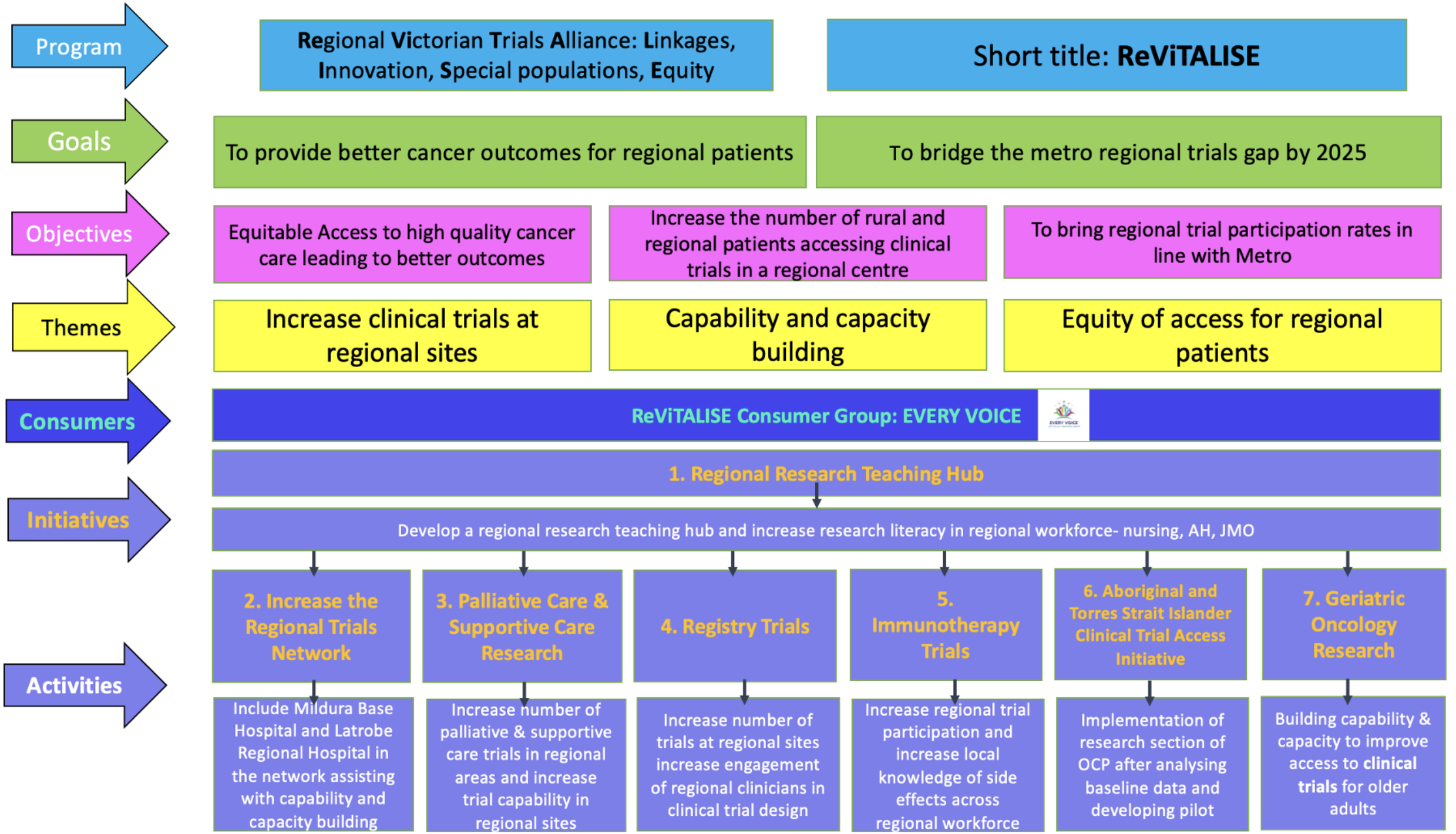
The Regional Trials Network - Victoria

Regional Trials Network Victoria



- Expand to 8 sites
- Catchment of 1.9 million people
- Over 7,200 new cancer diagnoses every year

Vic Cancer Plan 2020-2024:
Increase the overall number of new clinical trial enrolments in rural and regional areas in Victoria by 30%


Program
Regional Victorian Trials Alliance: Linkages, Innovation, Special populations, Equity
Short title: ReViTALISE
Goals
To provide better cancer outcomes for regional patients
To bridge the metro regional trials gap by 2025
Objectives
Equitable Access to high quality cancer care leading to better outcomes
Increase the number of rural and regional patients accessing clinical trials in a regional centre
To bring regional trial participation rates in line with Metro
Themes
Increase clinical trials at regional sites
Capability and capacity building
Equity of access for regional patients
Consumers
ReViTALISE Consumer Group: EVERY VOICE
Initiatives
1. Regional Research Teaching Hub
Develop a regional research teaching hub and increase research literacy in regional workforce- nursing, AH, JMO
Activities
2. Increase the Regional Trials Network
3. Palliative Care & Supportive Care Research
4. Registry Trials
5. Immunotherapy Trials
6. Aboriginal and Torres Strait Islander Clinical Trial Access Initiative
7. Geriatric Oncology Research
Include Mildura Base Hospital and Latrobe Regional Hospital in the network assisting with capability and capacity building
Increase number of palliative & supportive care trials in regional areas and increase trial capability in regional sites
Increase number of trials at regional sites increase engagement of regional clinicians in clinical trial design
Increase regional trial participation and increase local knowledge of side effects across regional workforce
Implementation of research section of OCP after analysing baseline data and developing pilot
Building capability & capacity to improve access to clinical trials for older adults

Addressing need to embed TT:
Four significant teletrial programs in Victoria

Australian Teletrials Program (funded by MRFF $75.2m, Implemented in Victoria by Dept of Jobs Precincts and Regions)

Regional Trials Network-Victoria and ReViTALISE program (RTN funded by Vic Cancer Agency; ReViTALISE projects funded by MRFF $18.6m)

TrialHub Alfred Health (funded by Govt of Australia, Department of Health $24.6m)

Victorian Comprehensive Cancer Centre Alliance (VCCC Alliance) Strategic Research Plan – Fast Track Innovations in regions with poorest outcomes (funded by Victoria Department of Health)

Victorian Teletrials Collaborative

AlfredHealth

VCCC Alliance

Regional Trials Network Victoria

Pre- pandemic use of telehealth

FDA Guidance: Conduct of clinical trials during pandemic : March 2020 (updated August 2021)

- Sponsors, clinical investigators, and IRBs should consider establishing and implementing policy and procedures, or revise existing policy and procedures, to describe approaches to be used to protect trial participants and manage study conduct during possible disruption of the study as a result of COVID-19 control measures at study sites. Changes to policy and procedures could address, but not be limited to, impact on the informed consent process, study visits and procedures, data collection, study monitoring, adverse event reporting, and changes in investigator(s), site staff, and/or monitor(s) secondary to travel restrictions, quarantine measures, or COVID-19 illness itself. Policy and

CARE DELIVERY

Telehealth in Oncology: ASCO Standards and Practice Recommendations

Robin T. Zon, MD[1]; Erin B. Kennedy, MHSc[2]; Kerin Adelson, MD[3]; Sibel Blau, MD[4]; Natalie Dickson, MD[5]; David Gill, MD[6]; Nicole Laferriere, MD[7]; Ana Maria Lopez, MD, MPH[8]; Therese M. Mulvey, MD[9]; Debra Patt, MD[10]; Todd A. Pickard, MMSc[11]; Terry Purdom[12]; Trevor J. Royce, MD, MS, MPH[13,14]; Ashley L. Sumrall, MD[15]; and Ray D. Page, DO, PhD[16]

JCO Oncol Pract 17:546-564.

6. Teletrials and/or virtual participation in oncology clinical trials

Standard 6.1

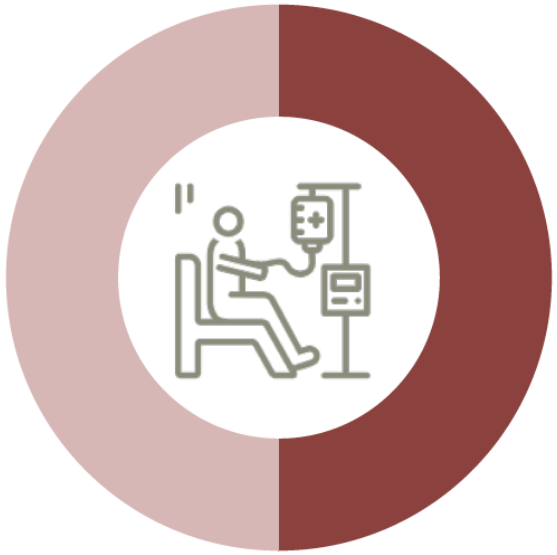
Teletrials and/or virtual participation in oncology clinical trials are recommended as a method of increasing recruitment and reducing the burden of trial participation on patients.

- To facilitate the conduct of teletrials, the following are recommended:
  - Virtual initial discussion of trial and eligibility assessment;
  - Incorporating remote methods of reviewing symptoms and adverse events, such as patient portals, e-mail, telephone, and video[24];
  - Remote study initiation and monitoring from sponsors and contract research organizations[24];
  - Shipping oral drugs directly to patients with a follow-up call to ensure the delivery and integrity of the agents and patient comprehension of the dosing schedule[24];
  - Increasing support for secure virtual platforms[25];
  - Allowing laboratory, for example, blood tests and biopsies to be conducted at a site that is local to the trial participant[25];
  - Reconsidering the necessity of frequent testing, including imaging[25];
  - Increasing the use of patient-reported outcomes as study outcomes.[25]

Qualifying statements

- This recommendation applies beyond the timeframe of the period of restrictions necessitated by the COVID-19 pandemic.
- Consider a hub and spoke model to improve participation among rural and remote populations (see *Australasian Teletrial Model*).[26]

Teletrials Benefits: Patient Recruitment



50% of sites
enroll one or no patients in studies

85% of clinical trials
Fail to retain enough patients

80% of all clinical trials
Fail to finish on time

TARGET-TP: phase 3 RCT

Utilising the teletrial strategy for access and advancement of science

Kate Burbury MBBS(Hons) FRACP FRCPA DPhil

Haematologist, Director Digital and Healthcare Innovations

Peter MacCallum Cancer Centre and Melbourne Health

On behalf of the TARGET-TP trial team

VCCC Alliance

Supported by

VICTORIA State Government

Clinical Oncology Society of Australia

COSA'S 48TH ANNUAL SCIENTIFIC MEETING

16-18 November 2021

100% Digital & ONLINE

Presented by

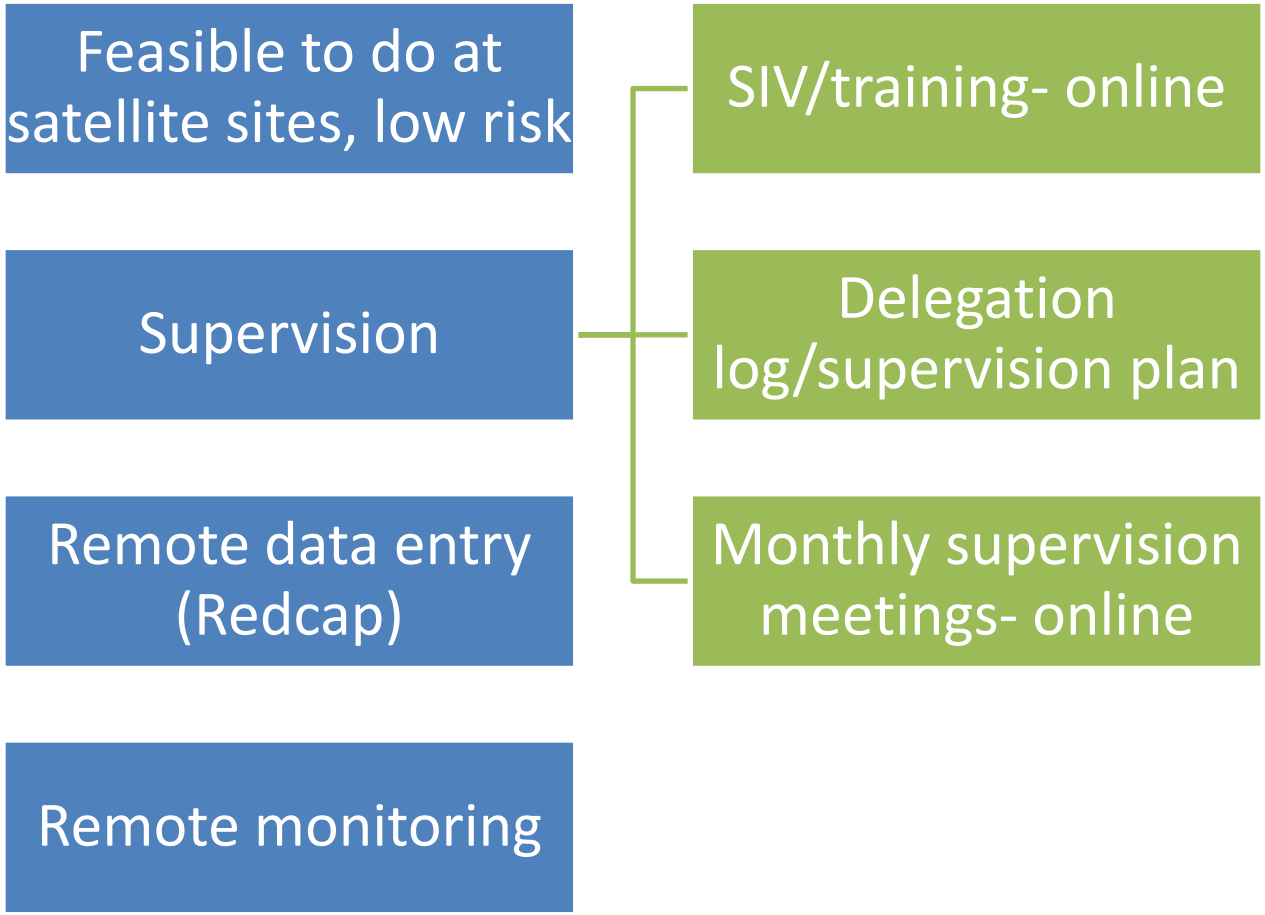
Insert name here

Insert twitter handle here

20 Cancer care and research: Learning from the past and Improving the future

ASM Immunotherapy PROMs and PREMs 21

Some aspects of COSA TT model used for conduct TARGET-TP



Proof concept - TARGET-TP - PROGRESS: Sept 2021

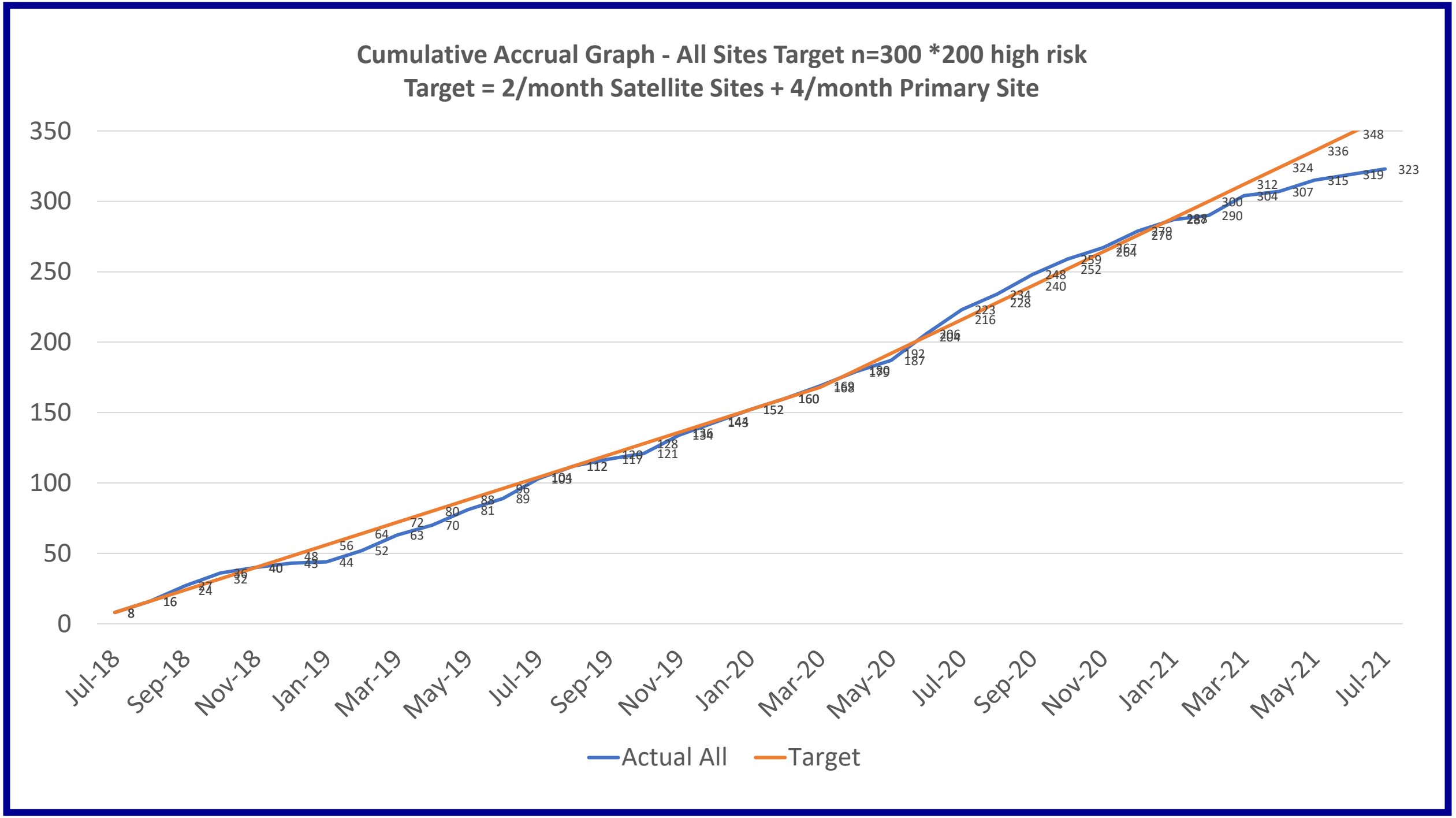
Key Dates	First patient on study
Peter Mac	28/06/2018
Border	10/01/2019
Bendigo	30/01/2019
Ballarat	15/04/2020
Shepparton	01/06/2020

Enrolment	No. (target)
Peter Mac	176 (160)
Border	61 (60)
Bendigo	74 (60)
Ballarat	5 (28)
Shepparton	12 (28)
Screen Fail	6 *due to TE or indication for therapeutic coag at Dx
On study	328

Completed accrual, last pt. enrolled June 2021
Target = 200 in high risk randomised cohort
Primary Endpoint Dec 2021

Risk stratification	No.	%
High risk PTP	*100* ** Target 100*	*30%*
High risk Control	*100* **Target 100*	*30%*
Low risk Observation	*128*	*39%*

Regional: 152
46%


Cumulative Accrual Graph - All Sites Target n=300 *200 high risk
Target = 2/month Satellite Sites + 4/month Primary Site
350
300
250
200
150
100
50
0
Jul-18
Sep-18
Nov-18
Jan-19
Mar-19
May-19
Jul-19
Sep-19
Nov-19
Jan-20
Mar-20
May-20
Jul-20
Sep-20
Nov-20
Jan-21
Mar-21
May-21
Jul-21
Actual All
Target

Rigorous Evaluation

JAMA Oncology Sept 2023 Risk-Directed Ambulatory Thromboprophylaxis in Lung and Gastrointestinal Cancers The TARGET-TP Randomized Clinical Trial doi:10.1001/jamaoncol.2023.3634

IQVIA audits x2 *-no major findings of any deviation of the Target TP trial from the operational process for Teletrials*

Consumer Perspectives Qualitative Study- *https://doi.org/10.1177/1357633X20950180*

Teletrials Online Education Module- *https://www.viccompcancerctr.org/what-we-do/clinical-trials-expansion/teletrials/online-modules/*

Implementation Toolkit *– https://www.viccompcancerctr.org/what-we-do/clinical-trials-expansion/teletrials/resources/*

Teletrials: implementation of a new paradigm for Clinical Trials (MJA) *https://doi.org/10.5694/mja2.50741*

Health Economic Evaluation-Dec 2023 Telehealth in oncology: a cost analysis to evaluate the financial impact of implementing regional trial hubs within a phase 3 cancer clinical trial https://doi.org/10.1111/imj.16292

JAMA Oncology Feb 2024 **Special Communication: Decentralized Clinical Trials as a New Paradigm of Trial Delivery to Improve Equity of Access** doi:10.1001/jamaoncol.2023.6565

TT v DCT

JAMA Oncology | Special Communication

Decentralized Clinical Trials as a New Paradigm of Trial Delivery to Improve Equity of Access

Craig Underhill, MBBS; Jessica Freeman, RN, MCLinExPhys; Jacqueline Dixon, RN; Mark Buzza, PhD; Donna Long, RN; Kate Burbury, MBBS, DPhil; Sabe Sabesan, PhD; Jacqueline McBurnie, RN; Anne Woollett, BEd, RN

Table 2. Differences Between the Clinical Oncology Society of Australia (COSA) Teletrial Model and Decentralized Clinical Trial

Issue	Teletrial[a]	Decentralized clinical trial
Patients receive care away from central institution	Yes	Yes
Site delegation log at trial site (ICHGCP requirement)	Yes	Yes
Supervision plan in place (COSA teletrial model requirement)	Yes	No
Conduct of study across a network, with comanagement of trial subject	Yes	Possibly
Upskilling of staff at partner sites	Yes	Possibly
Development of networks	Yes	Possibly
Digital tools may be used (including telehealth for consultations or digital data collection)	Yes	Yes

Abbreviation: ICHGCP, International Committee on Harmonization of Good Clinical Practice.

[a] Networked clinical trial is a synonym.

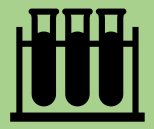
Teletrials Framework

Key components for implementation

Teletrials to be conducted in accordance with ICH-GCP and meet all regulatory requirements as governed by local and state jurisdictions for clinical trials

Feasibility

Site capacity, capability, trial complexity and sponsor acceptance will determine whether teletrial is feasible



Study Conduct

The principle investigator is responsible for the overall conduct of the study across all sites in the cluster according to GCP

Regulatory

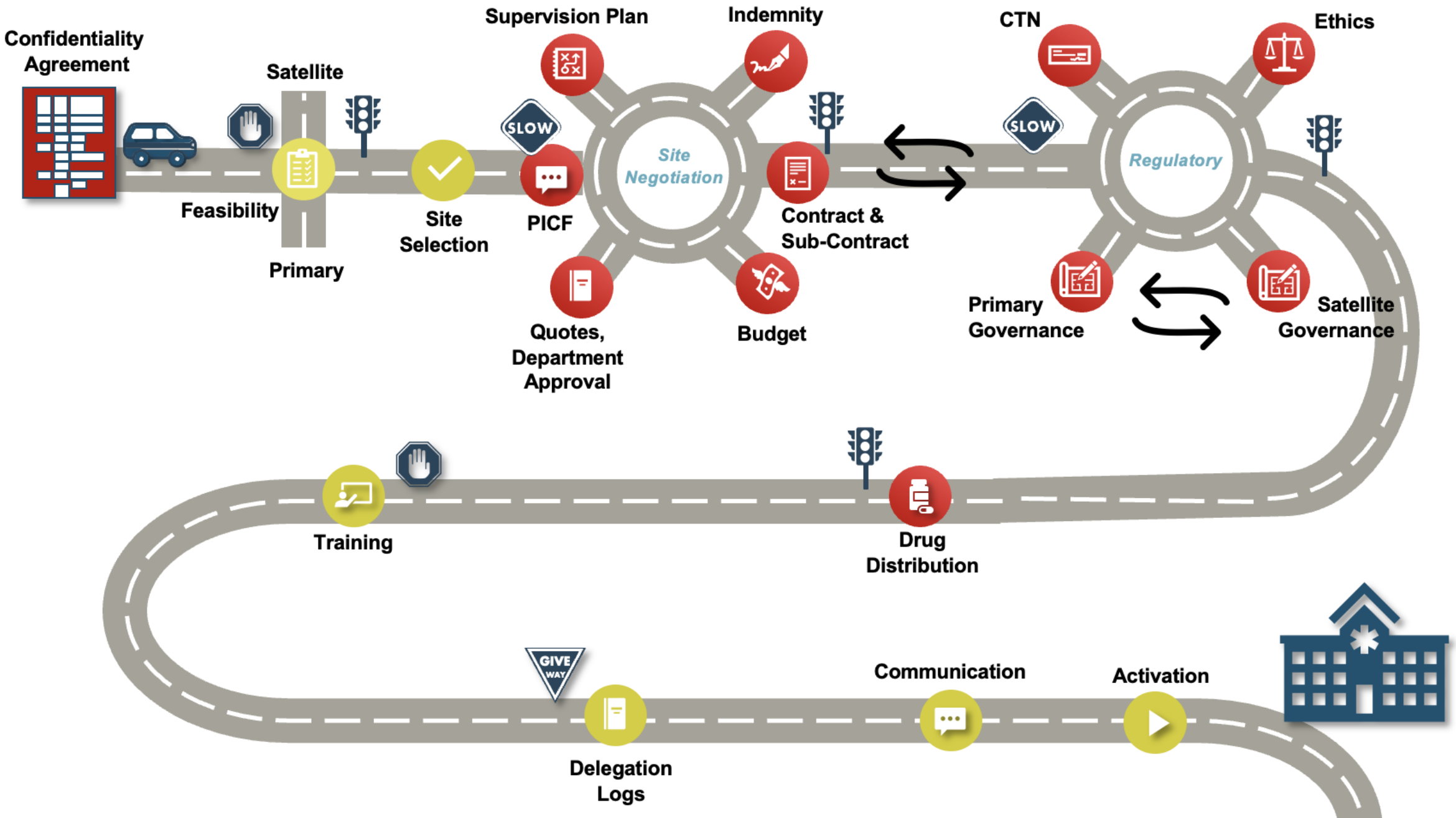
Most regulatory aspects already governed by local and state jurisdictions with minor amendments or creation of new templates for the model

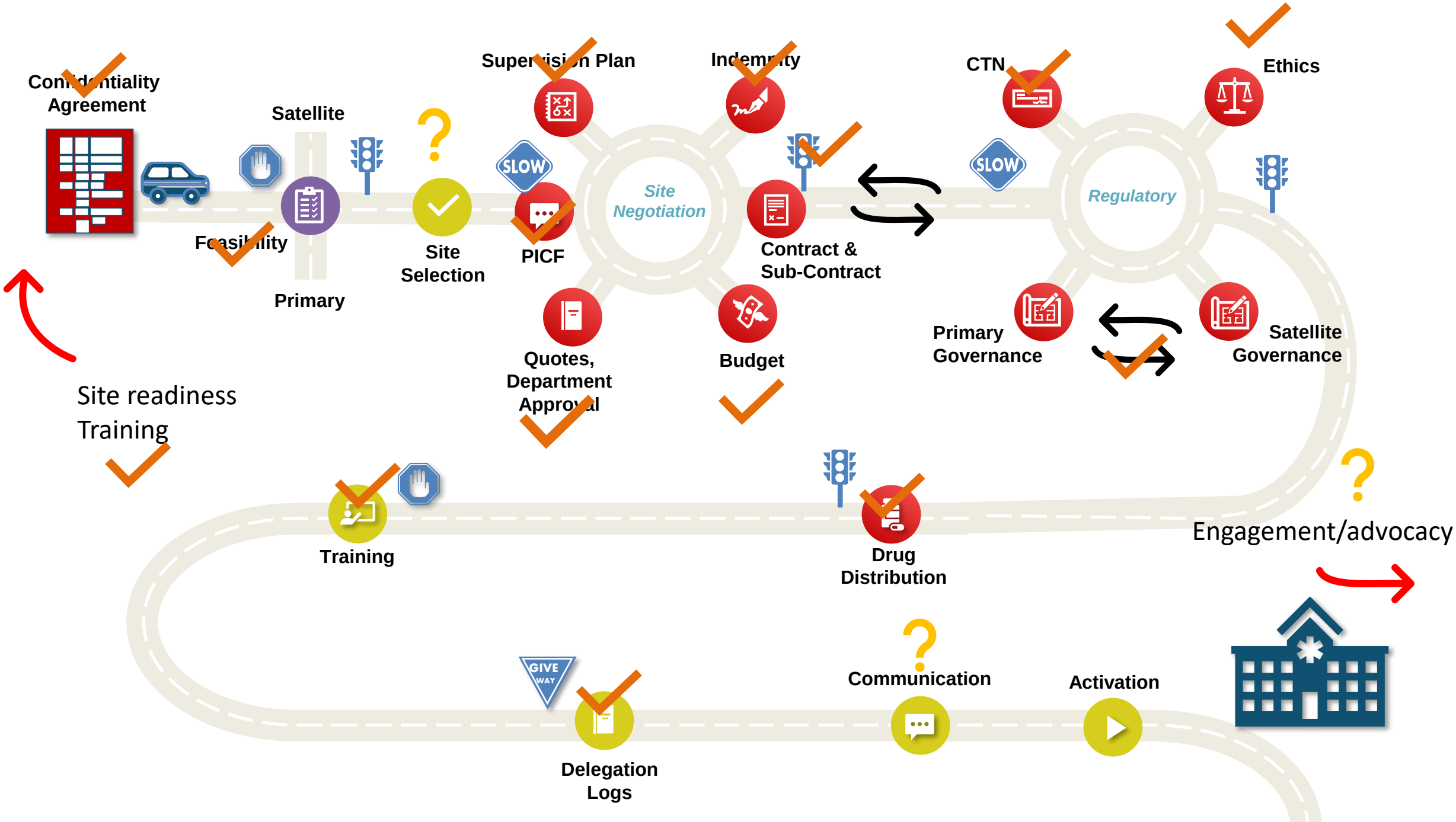
Data Management

Process for ensuring the transfer of reliable source documentation to primary site in the absence of state wide EMR system

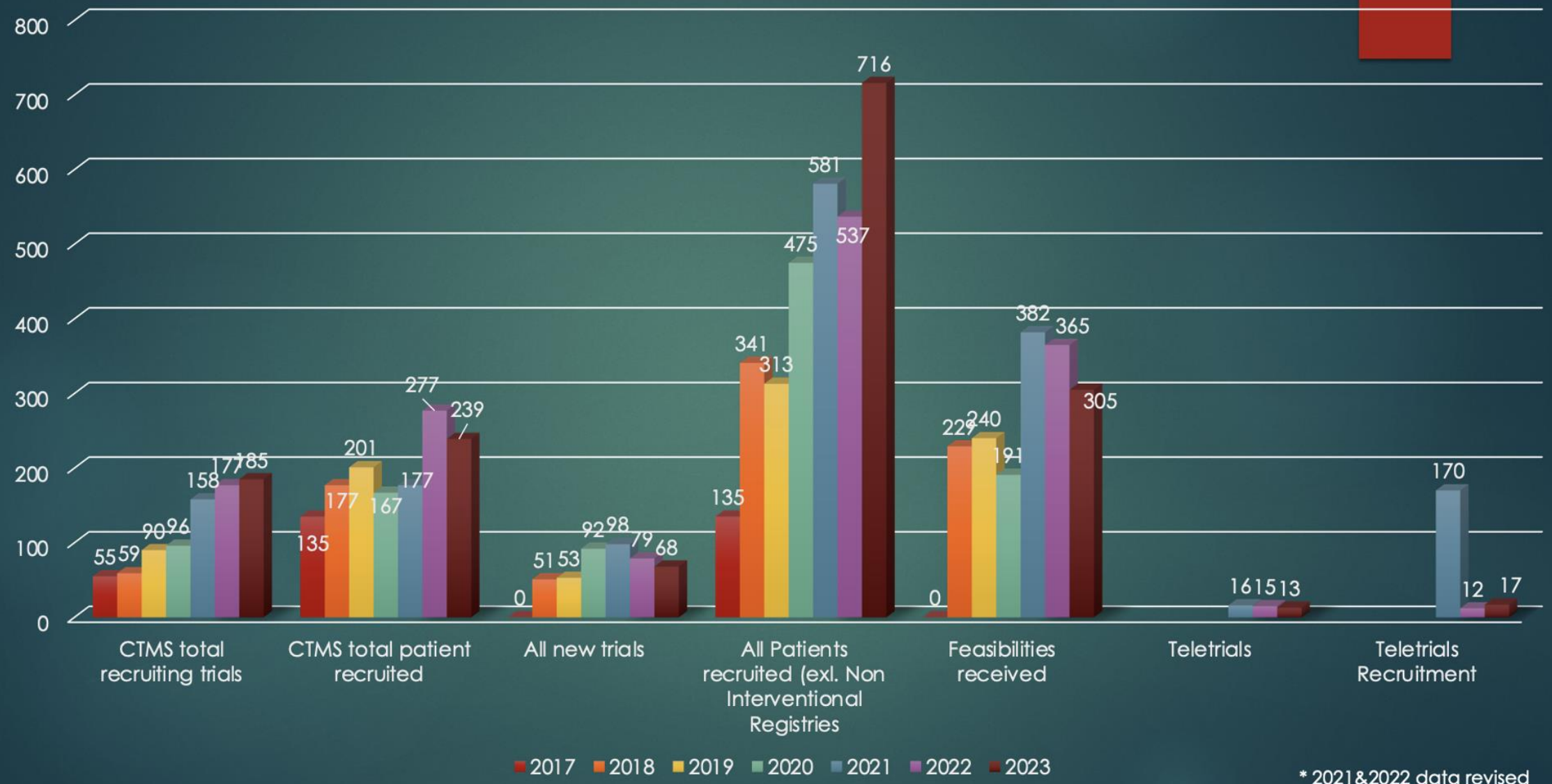
Pharmacovigilance

Same TGA requirements for both the primary and satellite sites


Confidentiality Agreement
Satellite
Feasibility
Primary
Site Selection
Supervision Plan
Indemnity
SLOW
PICF
Site Negotiation
Contract & Sub-Contract
Quotes, Department Approval
Budget
CTN
Ethics
SLOW
Regulatory
Primary Governance
Satellite Governance
Training
Drug Distribution
GIVE WAY
Delegation Logs
Communication
Activation


Confidentiality Agreement
Satellite
Feasibility
Primary
Site Selection
Supervision Plan
PICF
Quotes, Department Approval
Indemnity
Site Negotiation
Contract & Sub-Contract
Budget
CTN
Ethics
SLOW
Regulatory
Primary Governance
Satellite Governance
Site readiness
Training
Training
Drug Distribution
Engagement/advocacy
GIVE WAY
Delegation Logs
Communication
Activation

RTN Sites Research Portfolio data 2017 to 2023*



* 2021&2022 data revised

Its not just trial recruitment: other benefits include …

- mentoring
- new networks/collaborations,
- Shared training and other resources
- improved capability and capacity at sites
- translational research opportunities
- leverage (MRFF and other grants)
- enabled effective regional consumer voice
- regular self audits and peer benchmarking
- Participate in innovation – TH, rare cancers, precision medicine

Enablers

increasing capacity and capability at regional sites

devolved governance

utilising Telehealth to conduct clinical trials, HSR and networking

focus on regional health issues

effective consumer engagement

health services research training and implementation

Australian Comprehensive Cancer Network

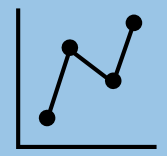
Standards of excellence for networked comprehensive cancer care in Australia

Australian Government
Cancer Australia

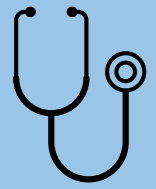
Deliver **comprehensive cancer care**

Deliver **equitable access** to **culturally safe care** across the cancer continuum

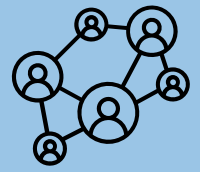
Deliver **research excellence**



Collect, share, and report **comprehensive cancer data** to drive service improvements and better cancer outcomes



Foster an **engaged, capable, and future focused** cancer workforce



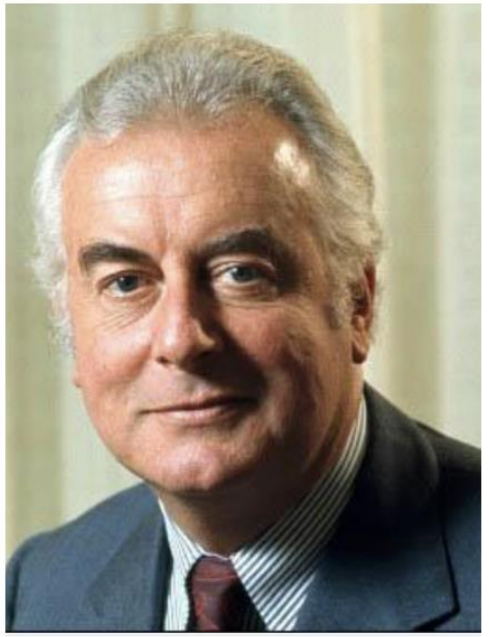
Deliver **connectivity and sharing of expertise** across the network

Self-evaluate performance and adherence with the standards of excellence

It’s Time!

By working across networks and using telehealth we have a generational opportunity to fundamentally change the clinical trial landscape in Aust and NZ and improve equity of access to clinical trials

- ✓ Clear evidence that we have a problem
- ✓ Common -sense solutions co-designed with people with cancer
- ✓ Support of people with cancer
- ✓ Policy support from government
- ✓ Engagement of industry, trialists
- ✓ Successfully conducted pilots/proof of principle
- ✓ Ongoing evaluation and improvement of model
- ✓ Cultural frameworks
- ✓ Funding



RTN-Vic members

Barwon Health

Cancer Trials Australia

Grampians Health

Bendigo Health

Latrobe Regional Health

Mildura Base Public Hospital

Albury Wodonga Health

GV Health

South West Healthcare

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Victorian Comprehensive Cancer Centre

TrialHub

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Australian Government
Department of Health

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Victorian Cancer Agency

Victoria