MRC-NIHR Trials Methodology Research Partnership: Webinar recording

# Data Integrity

***Presented by Liz Allen (Cape Town University), Philip Pallman (Cardiff University), Munya Dimairo (University of Sheffield), Alex Dmitrienko (Mediana)***

27 September 2022

On behalf of The Global Health Network

The slides are also available below.

For any queries, please contact uktmn@nottingham.ac.uk

**https://www.youtube.com/watch?v=bfw9dzwC1HU**

# TMRP Webinar Series 5
# The Global Health Network

# Tools and resources for adaptive designs in clinical trials

Tuesday 27 September 2022

# The Trials Methodology Research Partnership

- A global community of practice for improving the design, conduct, & analysis of trials everywhere
- The Global Health Working Group raises awareness of trials methodology research, signposting to technical working groups & training, facilitating collaborations & small methodology research grants for LMIC
- The Global Health Network joined the MRC-NIHR Trials Methodology Research Partnership to offer a gateway for researchers in LMICs to better contribute to & benefit from developments in this field

- Join any number of WGs & interact with a
  e, diverse membership
  : TMRP & TGHN websites for guidance,
  lications, webinars, networking
  www.methodologyhubs.mrc.ac.uk

ELSEVIER

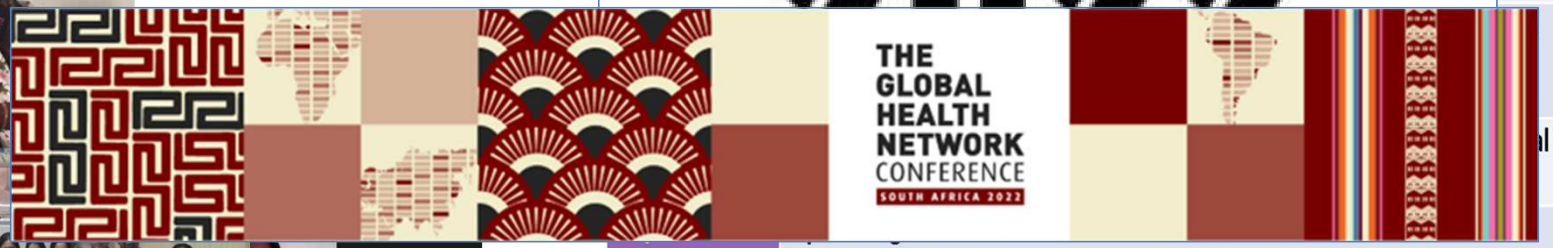
Contemporary Clinical Trials Communications

Volume 29, October 2022, 100959

# The practice of pilot/feasibility studies in informing the conduct of HIV relat clinical trials in sub-Saharan Africa scoping review

Sylivia Nalubega [a], Lawrence Obado Osuwat [a], Poku Brenda Agyeiwaa [b], John Bosco Matovu Junior [e]

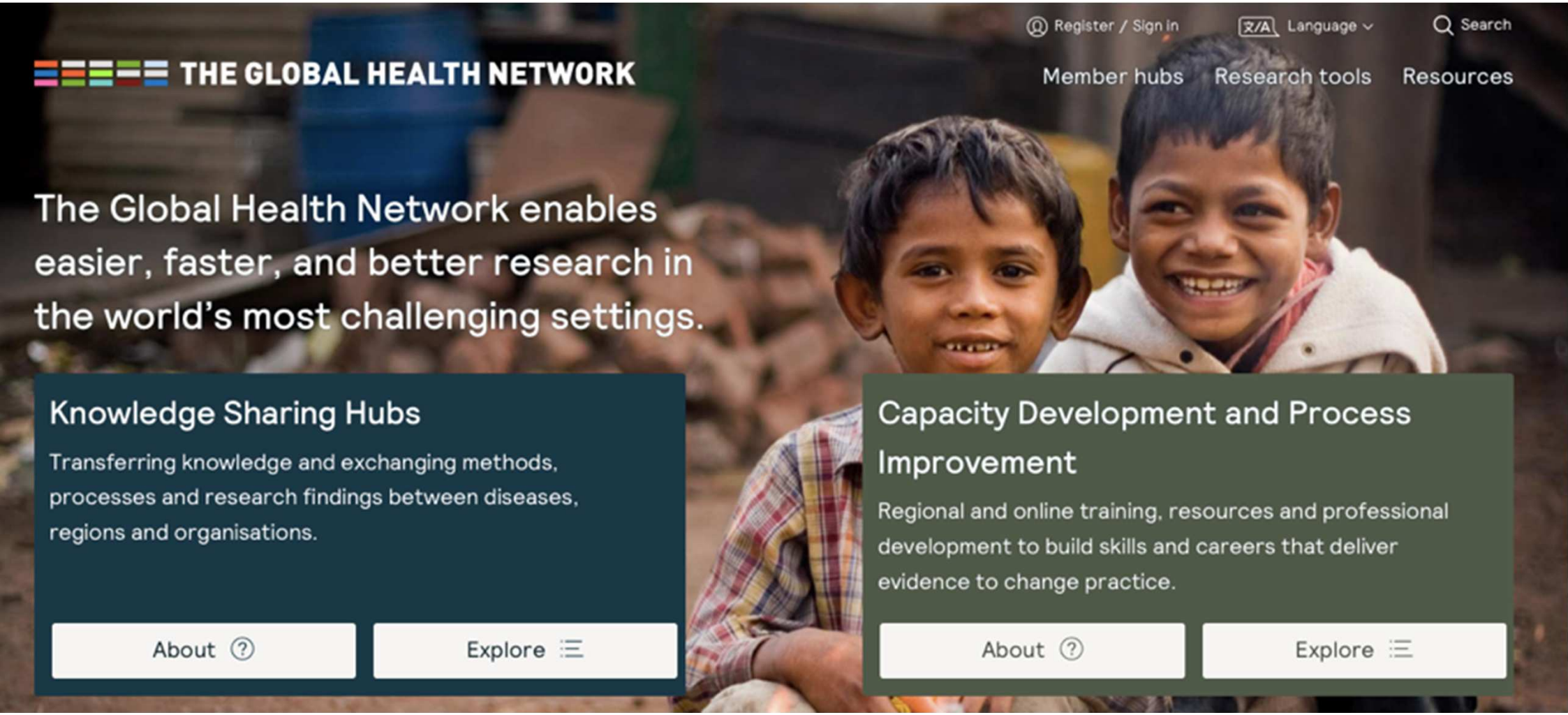
ICTMC 2022




| | |
|---|---|
| | settings: feasibility of an adapted QuinteT Recruitment Intervention (QRI) in India (OrION-I) |
| Thailand | Exploring **barriers to data reuse** |
| South Africa | **Cultural competence in trial design and conduct** |

# The Global Health Network

THE GLOBAL HEALTH NETWORK
Enabling research by sharing knowledge



# Proud partner of the TMRP

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Global Health Methodology Research

What are you looking for? SEARCH

Home | About Us | Resources | Global Methodology Projects | MRC/NIHR Trials Methodology Research Pa

Get started

## Home

This is a community of researchers who are interested in supporting the generation of mo
improvements in health across the globe. Clinical research needs evidence-led improved methods.

**What is methodology Research? Methodology Research is research about the way we design, conduct, analyse, re
Conducting methodology research research studies will generate evidence-led improvements in the way we desig
research on research! For examples of methodology research, vistit the MRC-NIHR Trials Methodology Research Pa**


TMRP Global Health Pump Priming Awards

**1. Photovoice to explore community members perspectives regarding he**

PI: James O'Donovan and David Musoke, Makerere University School of Public

There have been calls for a greater number of clinical studies in low- and mid
ensuring they are contextually relevant. One useful approach towards this is C
involves local stakeholders being central to the research process. CBPR is ofte
research remains contextually relevant and better understand the lived experi
suggested as a means of diversifying participation and increasing relevance ar
method aligned to CBPR is photovoice, whereby cameras are given to individu
community importance or concern. In our project, the subject of interest is cor
15 community members from the Seeta Nazigo Parish, Mukono District in cent
in the use of cameras and have undergone one round of photographic capture


## Conclusion

- The TMRP has contributed to equity in where research happens & who benefits.
- Any trial team member can explore optimal methods whatever their role
- Being part of this community can help with developing skills needed to answer questions about the way you design, operationalise, analyse & report your trials
- Including patients & participants in finding new & better trials methods is key
- Funders should consider investing in methods research within or alongside trials as a cost-effective way to sustain sites while improving the science of trials.
- It is also an excellent career development opportunity for early career researchers

- All diseases need an ecosystem of different types of research
- Each study requires a cycle of steps for accurate, safe & ethical data
- Findings should then be taken up into practice and policy

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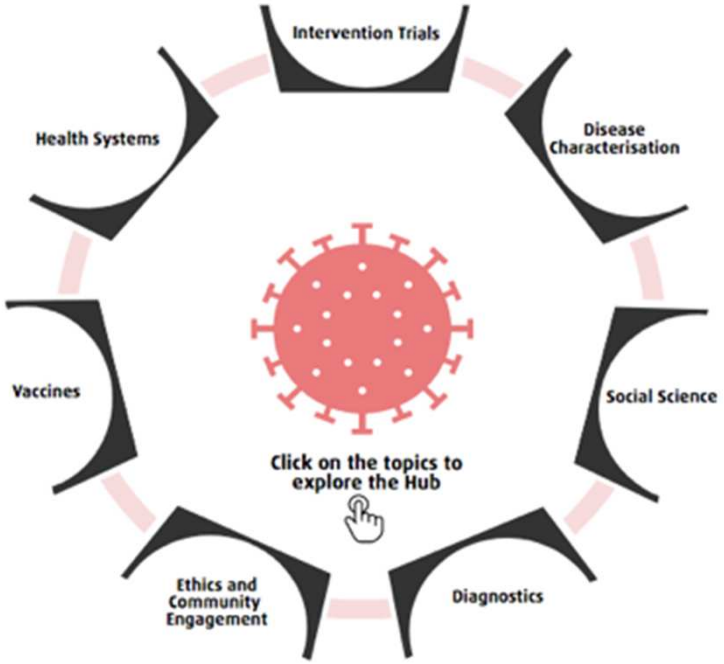


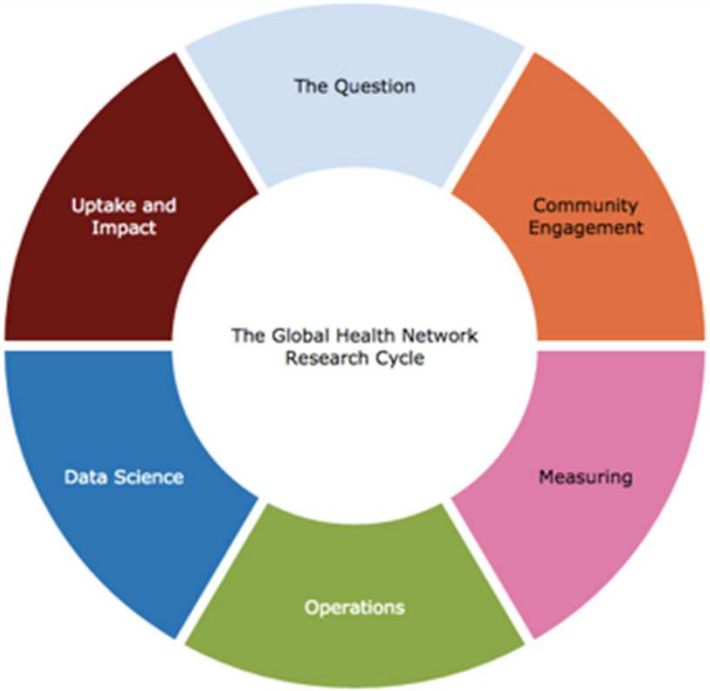


Steps & processes do not differ between diseases/type of research

Need to address gaps in evidence & tackle research inequity by sharing knowledge & know-how between diseases, organisations & settings

And embed research in every healthcare setting

# A network of digital & physical spaces

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A powerful mechanism for exchanging know-how & mobilising information

Research capacity development & knowledge exchange delivered through overlapping & interconnected focus areas

Not duplicating, but connecting excellence


# Vast space for research organisations & networks to come together with research teams, health workers & policy makers

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Research skills training, career development & knowledge mobilisation

- **Online learning**
- **Webinars & workshops**
- **Regional capacity building programmes**
- **Resources & toolkits**
- **Process mapping**
- **Education & tacit learning**
- **Professional Development for researchers**
- **Essential Curriculum for health research**

***Over 3 million courses taken***
***100,000's documents shared***
***Standards raised by providing access to tools, methods and how-to***
***Delivering equity to access to knowledge***


Over 60 knowledge Hub exchanging how-to between diseases, regions & teams

This works as the barriers don't differ

Embedded with research capacity building mechanisms to develop lasting capable teams

# Communities of practice building lasting capable research teams

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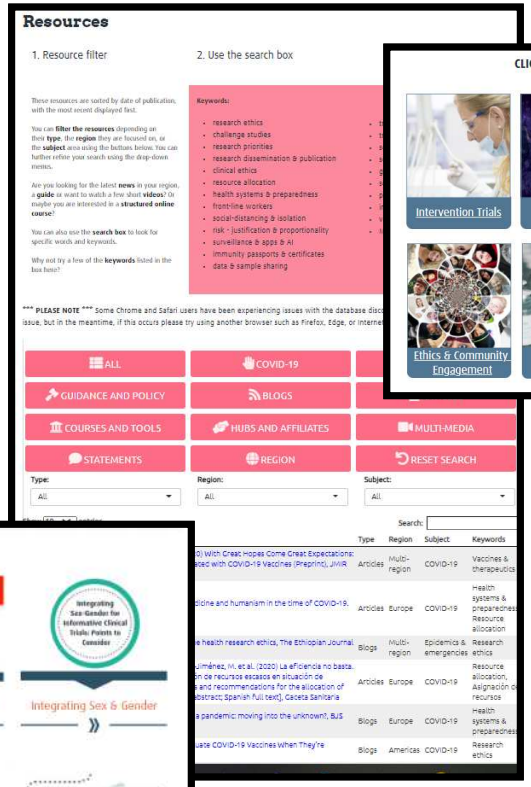



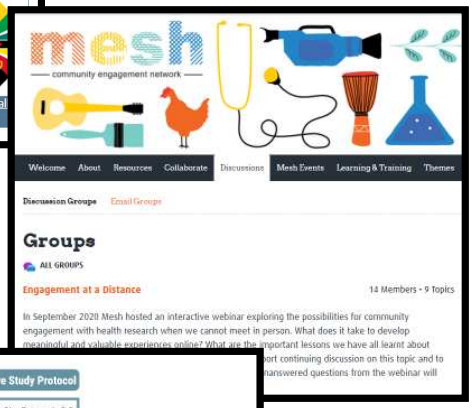



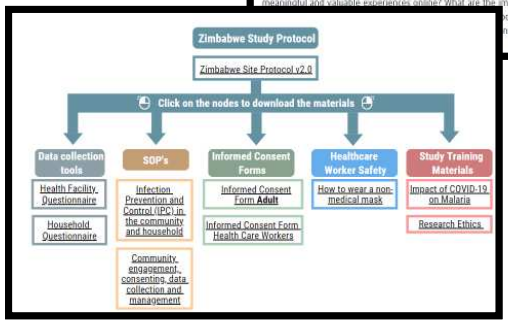

# Myriad types of resources

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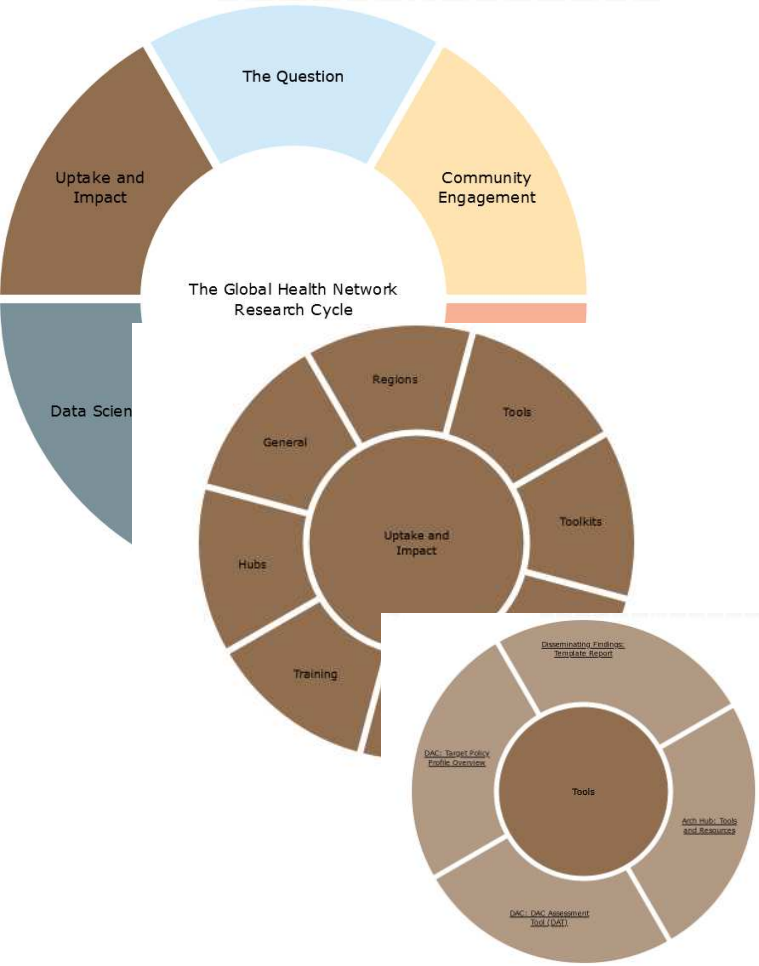
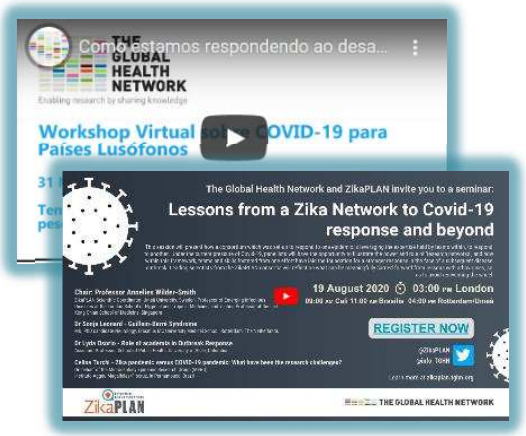



## Courses


= Training, strengthen skills base

## Webinars




= Deliver, debate & share, lessons learnt, wider dissemination

## Project materials


= Download, modify & re-use

## Apps & toolkits


= Adapt & replicate

# Certified open access eLearning:
# 130+ courses with 80+ translations

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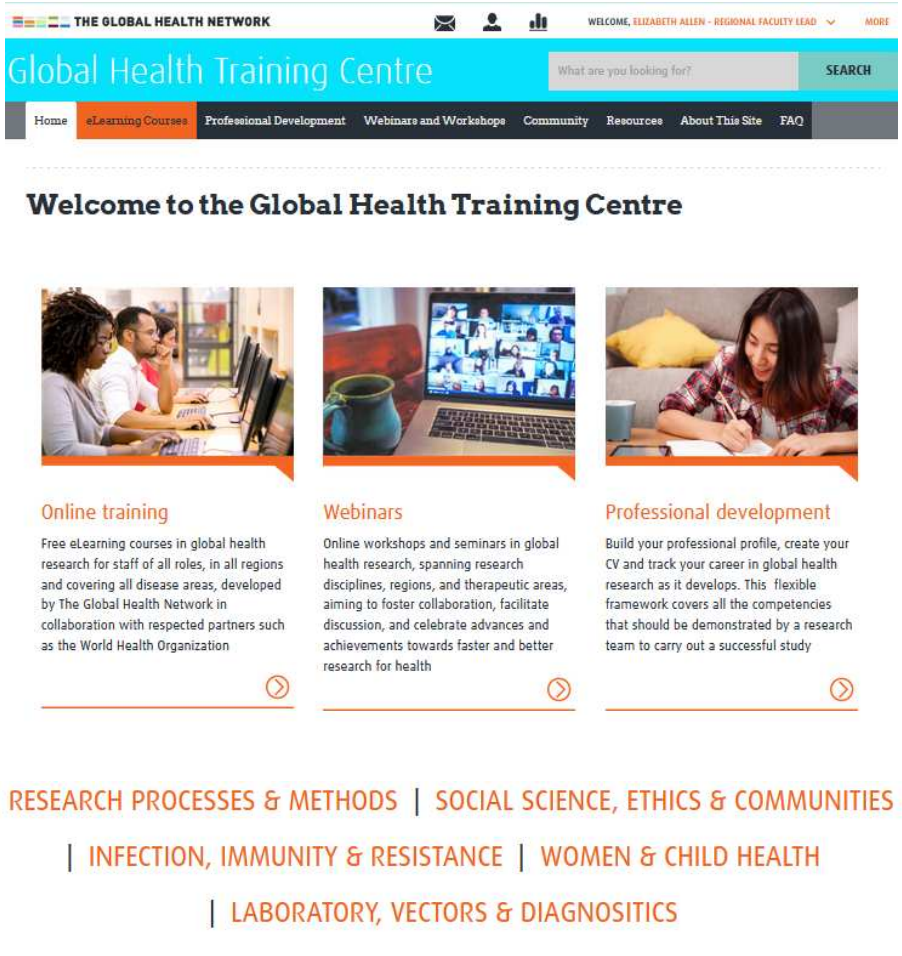


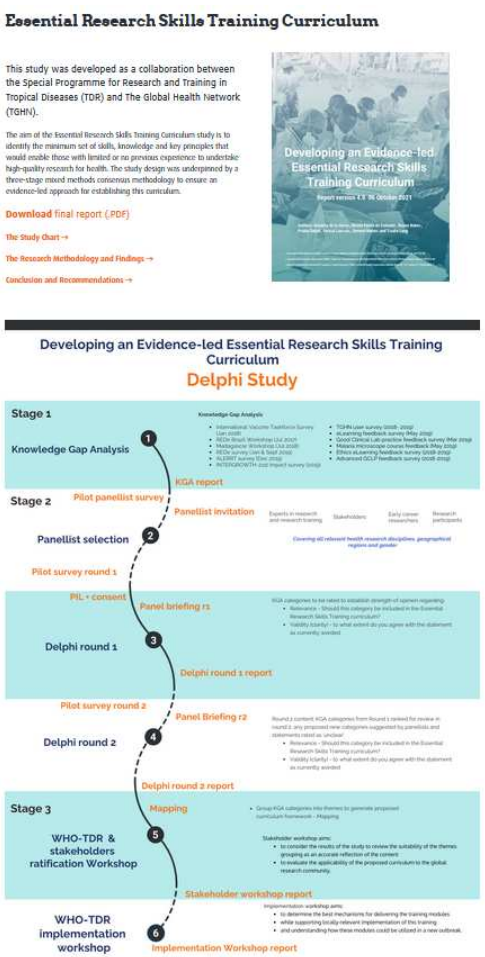



- Many different collaborators
- Open access, globally applicable
- Peer reviewed, regularly updated
- Certificate issued > 80% in quizzes
- > 500,000 people taken courses

# Sharing expertise through webinars

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## Workshops

Workshops are a valuable and engaging way to learn, providing a fantastic opportunity for collective training sessions, skills transfer, networking and information sharing.

The range of workshops and format for delivering these sessions can be creatively designed to best serve the context of the learning. Initiatives such as these help to support and strengthen capacity at both an individual and institutional level. We set-up and facilitate a wide range of practical workshops in close collaboration with coordinators and study teams in diverse settings. Please do review the variety of workshops hosted across the regions that cover a breadth of topics, which have generated rich outputs from these sessions to benefit researchers globally.

### AFRICA

- Research in Global Health Emergencies
- Africa CDC One Health workshops
- Research Ethics during Epidemics
- Laboratory Quality Control
- Infection Prevention and Control AMR
- Grant Writing Workshop
- Introduction To Scientific Writing
- Laboratory Quality Control
- PC-NTDs Workshop
- Nigeria Workshop 2021
- Treatment protocols and approaches from different countries: The African Story
- Africa's capacity for real-time polymerase chain reaction (RT-PCR) diagnosis of infectious diseases
- Implementation of Novel Diagnostics
- Improving clinical trial conduct in Africa

### Migrant Communities and the COVID-19 Pandemic: Ethical considerations

**Mon 6th Jun 1:00pm - 2:00pm (BST)**

During the COVID-19 pandemic, migrants have often been denied rights and placed in situations which put them at heighted risk of disease. This webinar looks at migrant communities' explicit and implic ...

### Richard T Johnson Lecture | Neurologic morbidities from pediatric cerebral malaria—Looking Beyond the Body Count

**Tue 14th Jun 2:00pm (BST)**

Neurological infectious diseases pose some of the greatest challenges to clinicians. The presenting clinical syndromes are often elusive, determining the causative organisms can be problematic, and th ...

### Indigenous communities, 'vulnerability', and the COVID-19 pandemic

**Mon 20th Jun 1:00pm (BST)**

Indigenous populations around the world have historically experienced–and continue to experience–both social and economic marginalization, and as a result are at disproportionate risk during public

### Introduction to Research for nurses and midwives

**Thu 23rd Jun 12:00pm - 1:00pm (BST)**

Global Research Nurses mission is to empower nurses and midwives to get involved in research, no matter where they work or the role they undertake. This webinar will inspire you to get started in rese ...

### Global Brain Health Clinical Exchange Platform – Critical Care of the Neurologic System in COVID-19

**Fri 24th Jun 2:00pm - 3:00pm (BST)**

In this interactive workshop, Dr. Ayush Batra will cover critical care of the neurologic system during acute COVID-19 Chair: Ass Prof (Dr) Sherry H-Y Chou Associate Professor of Neurology (Neurocritic ...

### Communicating Science to Facilitate the Uptake of Research Findings into Policy and Practice

**Tue 28th Jun 1:00pm - 3:00pm (BST)**

Part 2: How to write a policy brief Speaker: Dr Sohana Shafique A stakeholder mapping exercise conducted in March 2020 by the Applying Research to Policy and Practice for Health (ARCH) programme at th ...

# Supporting career development

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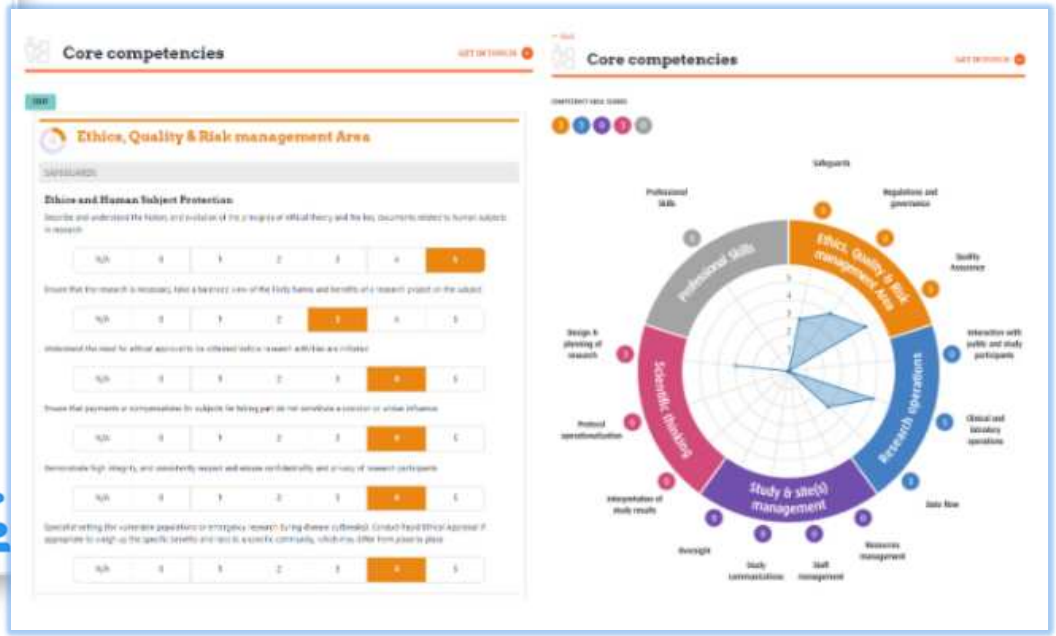
- Professional Development Scheme (PDS) created by The Global Health Network & WHO-TDR
- Records, tracks and guides professional development using *core competencies*
- Can aggregate data across teams = track and measure development over time


Needs assessment

Workshops

Twinning

Mentoring

# Increasing findability & attributing effort

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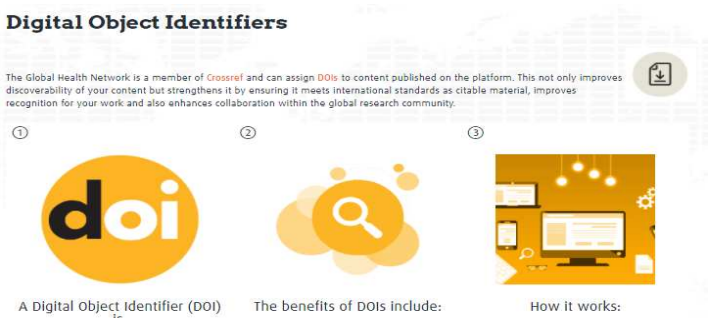
THE GLOBAL HEALTH NETWORK AFRICA

Home | Events | Workshops | Your Career | Toolkits | Resources | Topics | eLearning | Country Projects | Translate

## Resources

Resources actively guide, teach and train researchers in setting up and running high-quality studies

A range of resources exist to truly provide active and detailed support for implementing health research studies. This includes the provision of openly accessible study documentation presented in **study profiles**, which can be downloaded and adapted to suit various study designs and settings. Structured guidance is available through the **process map** to methodically walk researchers through the various steps in the design and operational set-up of a study. Free **eLearning** courses afford the opportunity to engage in wider skills-based training, including the fundamental basics, and more specialist modules.

# Methodology research: mixed methods → data from 7000+ individuals in 153 countries

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Open Access Research

BMJ Open

Understanding th
a qualitative stud
the barriers and
to the impleme
investigator-in
in Ethiopia

Samuel R P Franzen,[1] Cla
Julius Atashili,[5] Brian Angu

Format: Abstract

BMJ Open. 2017 Oct 13;7(10):e017246. doi: 10.1136/bmjopen-2017-017246.

**Strategies for developing sustainable health research capacity in low and middle-income countries: a prospective, qualitative study investigating the barriers and enablers to locally led clinical trial conduct in Ethiopia, Cameroon and Sri Lanka.**

Franzen SRP[1,2], Chandler C[3], Siribaddana S[4], Atashili J[5], Angus B[6], Lang T[1].

Author information

Send to

Abstract

OBJECTIVES: In 2013, the WHO stated that unless low-income and
goals would be hard to achieve. Among the capacities
There is no evidence-based guidance for th
enablers to locally led clinical
DESIGN: Pros
exerci
SETTI
PARTIC
selected
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of research, health
ls is important.
e barriers and

mapping

purposively

using thematic coding anal

**Using The Global Health Network Community and Data to Assess Capacity for Regulatory Standard Clinical Research in LMICs**

The Global Health Network
February 2018

# Clinical trials: foundational & core, need to be informative

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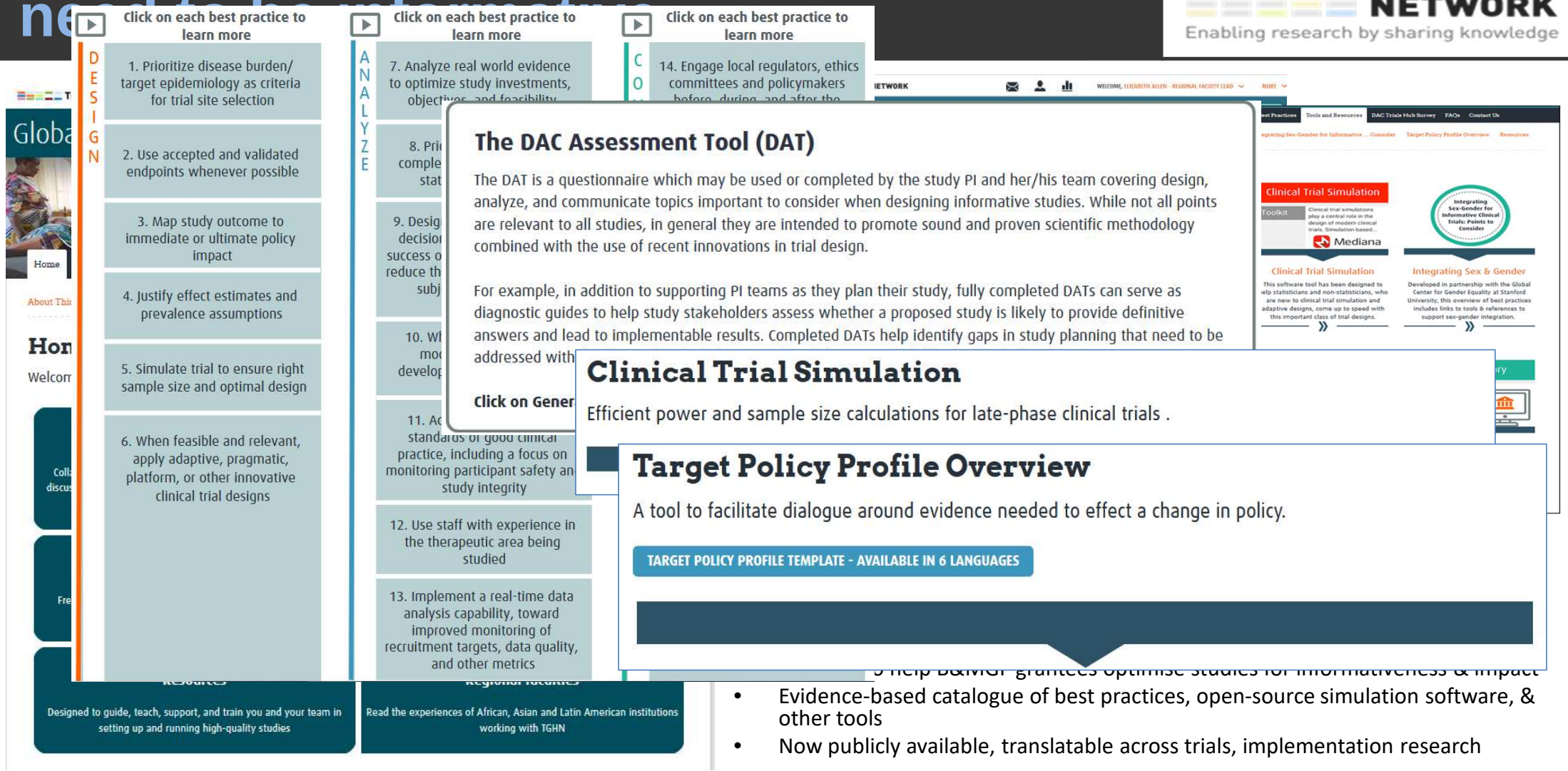


- Evidence-based catalogue of best practices, open-source simulation software, & other tools
- Now publicly available, translatable across trials, implementation research

# The next five years

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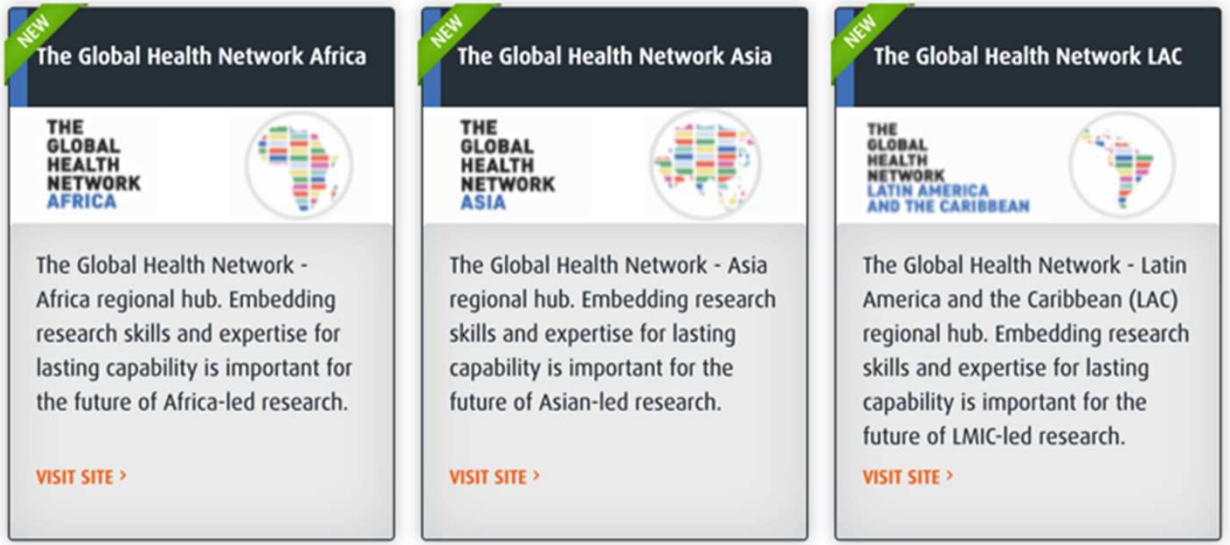



AFRICA CDC
Centres for Disease Control and Prevention
Safeguarding Africa's Health

icddr,b

FIOCRUZ

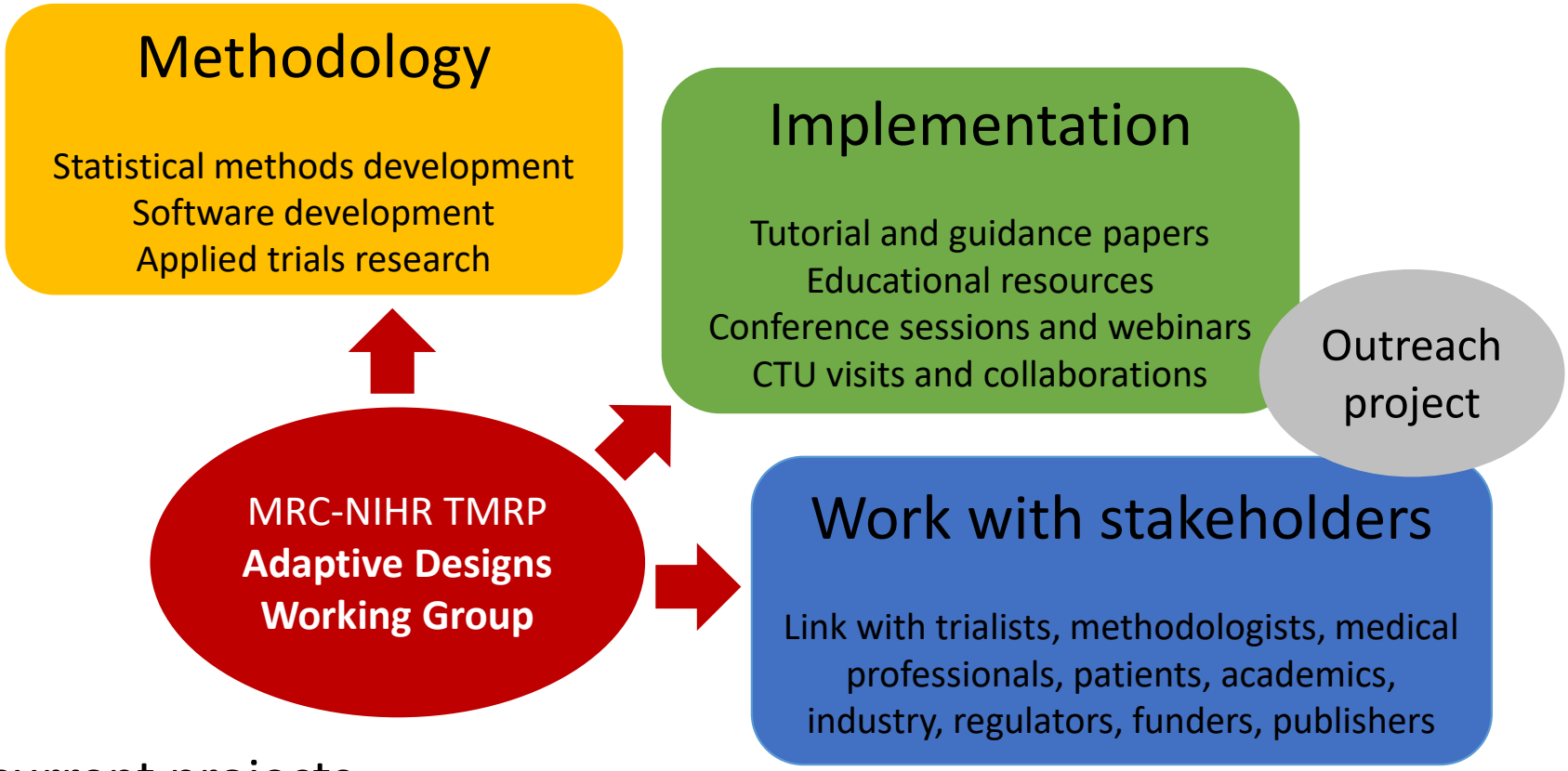
**1. Shift leadership to the Global South through three regional leadership centres**
**2. Take mechanisms for knowledge mobilisation, capacity building & connecting excellence to scale with out partners**
**3. Support the whole ecosystem for health research: embedding research everywhere**

WHO Collaborating Center for research information sharing, e-learning and capacity development

# Thank you!

**Elizabeth Allen**
**Co-Lead Global Health WG TMRP**
**TGHN Strategic Partnerships Lead**
**elizabeth.allen2@ndm.ox.ac.uk**

www.methodologyhubs.mrc.ac.uk
https://tghn.org/
https://dac-trials.tghn.org/




Selected current projects:

- sample size simulation
- patient information sheets
- estimands
- bias-adjusted point and confidence intervals estimation
- early phase reporting guidance

>30 active members from across the UK and Ireland

The ACE Project

Dimairo et al. BMC Medicine (2018) 16:210
https://doi.org/10.1186/s12916-018-1196-2

BMC Medicine

GUIDELINE Open Access

## Development process of a consensus-driven CONSORT extension for randomised trials using an adaptive design

Munyaradzi Dimairo[1*], Elizabeth Coates[1], Philip Pallmann[2], Susan Todd[3], Steven A. Julious[1], Thomas Jaki[4], James Wason[5,14], Adrian P. Mander[2], Christopher J. Weir[6], Franz Koenig[7], Marc K. Walton[8], Katie Biggs[1], Jon Nicholl[1], Toshimitsu Hamasaki[9], Michael A. Proschan[10], John A. Scott[11], Yuki Ando[12], Daniel Hind[1] and Douglas G. Altman[13*]

Dimairo et al. Trials (2020) 21:528
https://doi.org/10.1186/s13063-020-04334-x

Trials

METHODOLOGY Open Access

## The adaptive designs CONSORT extension (ACE) statement: a checklist with explanation and elaboration guideline for reporting randomised trials that use an adaptive design

Munyaradzi Dimairo[1*], Philip Pallmann[2], James Wason[3,4], Susan Todd[5], Thomas Jaki[6], Steven A. Julious[1], Adrian P. Mander[2,3], Christopher J. Weir[7], Franz Koenig[8], Marc K. Walton[9], Jon P. Nicholl[1], Elizabeth Coates[1], Katie Biggs[1], Toshimitsu Hamasaki[10], Michael A. Proschan[11], John A. Scott[12], Yuki Ando[13], Daniel Hind[1], Douglas G. Altman[14] and on behalf of the ACE Consensus Group

COSTING ADAPTIVE TRIALS

Wilson et al. BMC Medicine (2021) 19:251
https://doi.org/10.1186/s12916-021-02124-z

BMC Medicine

RESEARCH ARTICLE Open Access

## Costs and staffing resource requirements for adaptive clinical trials: quantitative and qualitative results from the Costing Adaptive Trials project

Nina Wilson[1], Katie Biggs[2], Sarah Bowden[3], Julia Brown[4], Munyaradzi Dimairo[5], Laura Flight[2], Jamie Hall[2], Anna Hockaday[4], Thomas Jaki[5,6], Rachel Lowe[7], Caroline Murphy[8], Philip Pallmann[7], Mark A. Pilling[9], Claire Snowdon[10], Matthew R. Sydes[11], Sofia S. Villar[5], Christopher J. Weir[12], Jessica Welburn[2], Christina Yap[10], Rebecca Maier[1,13], Helen Hancock[1,13] and James M. S. Wason[1*]

Wason et al. BMC Medicine (2022) 20:254
https://doi.org/10.1186/s12916-022-02445-7

BMC Medicine

CORRESPONDENCE Open Access

## Practical guidance for planning resources required to support publicly-funded adaptive clinical trials

James M. S. Wason[1*], Munyaradzi Dimairo[2], Katie Biggs[2], Sarah Bowden[3], Julia Brown[4], Laura Flight[5], Jamie Hall[5], Thomas Jaki[6,7], Rachel Lowe[8], Philip Pallmann[9], Mark A. Pilling[5], Claire Snowdon[10], Matthew R. Sydes[11], Sofia S. Villar[6], Christopher J. Weir[12], Nina Wilson[1], Christina Yap[10], Helen Hancock[13] and Rebecca Maier[13]

Pallmann et al. BMC Medicine (2018) 16:29
https://doi.org/10.1186/s12916-018-1017-7

BMC Medicine

CORRESPONDENCE Open Access

## Adaptive designs in clinical trials: why use them, and how to run and report them

Philip Pallmann[1*], Alun W. Bedding[2], Babak Choodari-Oskooei[3], Munyaradzi Dimairo[4], Laura Flight[5], Lisa V. Hampson[1,6], Jane Holmes[7], Adrian P. Mander[8], Lang'o Odondi[7], Matthew R. Sydes[3], Sofia S. Villar[8], James M. S. Wason[8,9], Christopher J. Weir[10], Graham M. Wheeler[8,11], Christina Yap[12] and Thomas Jaki[1]

Burnett et al. BMC Medicine (2020) 18:352
https://doi.org/10.1186/s12916-020-01808-2

BMC Medicine

CORRESPONDENCE Open Access

## Adding flexibility to clinical trial designs: an example-based guide to the practical use of adaptive designs

Thomas Burnett[1*], Pavel Mozgunov[1], Philip Pallmann[2], Sofia S. Villar[3], Graham M. Wheeler[4] and Thomas Jaki[1,3]

PANDA | A Practical Adaptive & Novel Designs and Analysis toolkit

# Find out more

http://www.methodologyhubs.mrc.ac.uk/about/working-groups/

# Get in touch

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# PANDA: A Practical Adaptive & Novel Designs and Analysis toolkit


**Munya Dimairo**

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m.dimairo@sheffield.ac.uk / mdimairo@gmail.com

Clinical Trials Research Unit, University of Sheffield

On behalf of PANDA team: Philip Pallmann, Graham Wheeler, Thomas Jaki, Mike Bradburn, Laura Flight, and Cindy Cooper



TMRP series - Global Health/Adaptive Designs Working Groups, 27th Sept 2022


PANDA

https://panda.shef.ac.uk/

The University Of Sheffield. Clinical Trials Research Unit.

# Funding declaration and disclaimer

This project received funding from the NIHR Clinical Trials Unit (CTU) Support Funding to support efficient/innovative delivery of NIHR research focusing on “developing skills for trials staff”.

The views or opinions expressed during this talk are mine and do not necessarily reflect those of the National Health Service (NHS), the National Institute for Health Research (NIHR), or the Department of Health and Social Care.

PANDA

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# Outline

- Brief background and the birth of PANDA
- Intended purpose and target audience
- PANDA platform features
- Wishes and the future
- Take a few questions

PANDA

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# Where we are coming from …

- Adaptive designs can be very efficient when used appropriately
- Their use in practice is steadily increasing
- Lack of practical knowledge among diverse stakeholders is still a persisting barrier
- A lot is being done and things are improving … but more still needs to be done!

PANDA

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# Back then … and the birth of PANDA

- Very limited practical training on adaptive designs
- Face-to-face tends to be expensive and inconvenient
- Training tends to target statisticians; other key stakeholders are left behind (clinicians, trial managers, proposal developers, etc)
- Extra burden on leading statisticians to educate trial teams throughout the trial cycle

This Photo by Unknown Author is licensed under CC BY-SA-NC

PANDA

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# Purpose of PANDA and target audience

- To bridge the practical knowledge gap in adaptive trial designs
- Offers self-paced practical learning
- Easily accessible to anyone involved in clinical trials research interested in learning about issues around adaptive trials
- Less technical language
- One-stop shop repository (e.g., guidance on specific topics)


Credit: https://coldsunflowers.co.uk/baby-steps/

PANDA

https://panda.shef.ac.uk/

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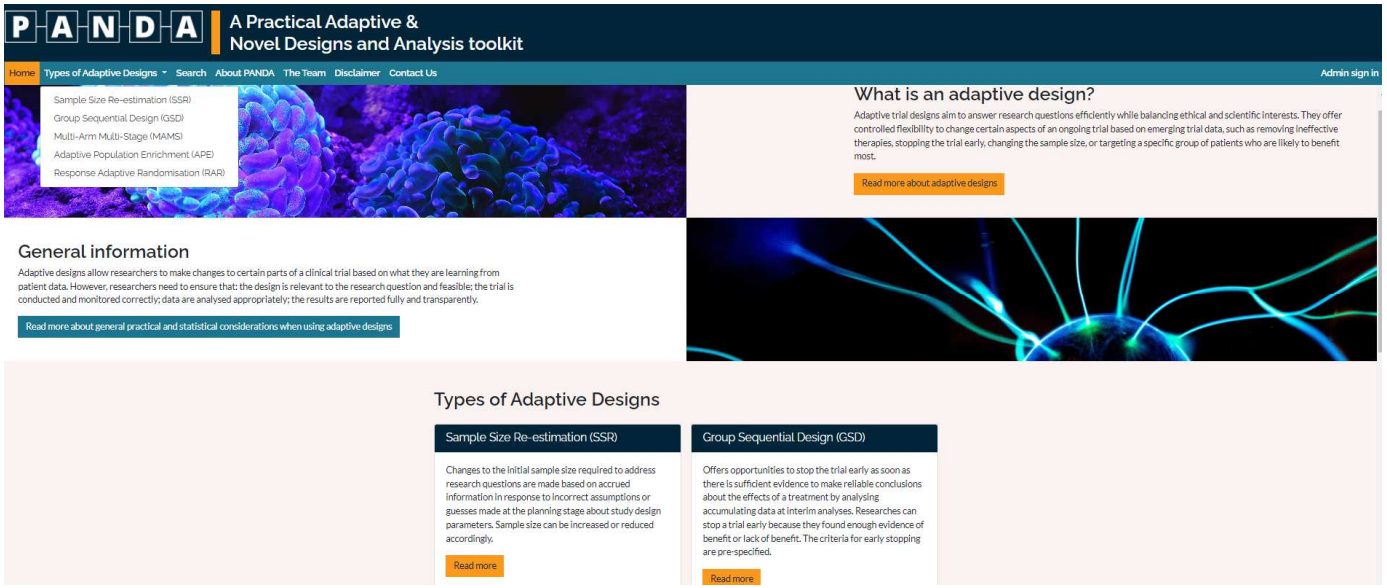
# Accessing PANDA: https://panda.shef.ac.uk/




- Linear structure
- Linked content
- Easy of navigation and to find content
- Defined technical terms
- Key references for further reading
- Link to related resources (e.g., Mediana)

PANDA

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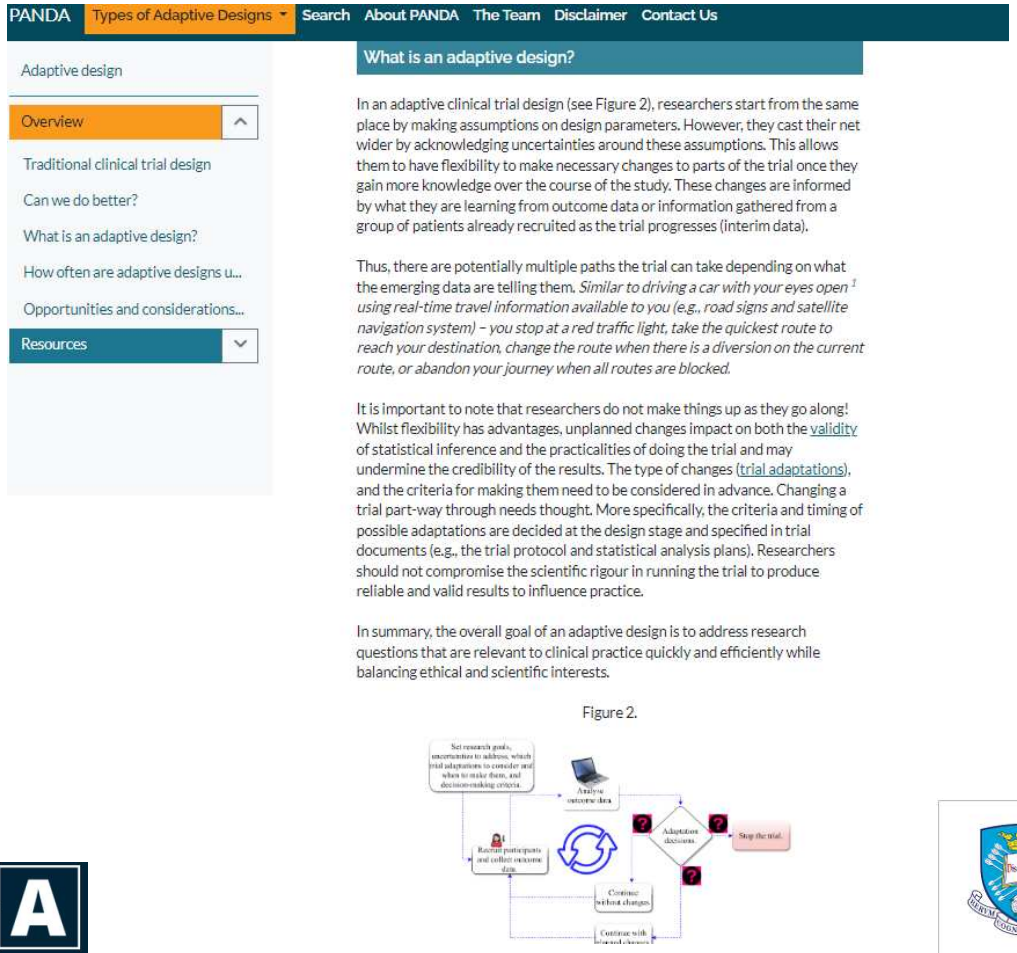
# I want to learn about an adaptive design …



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Adaptive design

- Overview
- Traditional clinical trial design
- Can we do better?
- What is an adaptive design?
- How often are adaptive designs u...
- Opportunities and considerations...
- Resources

## What is an adaptive design?

In an adaptive clinical trial design (see Figure 2), researchers start from the same place by making assumptions on design parameters. However, they cast their net wider by acknowledging uncertainties around these assumptions. This allows them to have flexibility to make necessary changes to parts of the trial once they gain more knowledge over the course of the study. These changes are informed by what they are learning from outcome data or information gathered from a group of patients already recruited as the trial progresses (interim data).

Thus, there are potentially multiple paths the trial can take depending on what the emerging data are telling them. *Similar to driving a car with your eyes open [1] using real-time travel information available to you (e.g., road signs and satellite navigation system) – you stop at a red traffic light, take the quickest route to reach your destination, change the route when there is a diversion on the current route, or abandon your journey when all routes are blocked.*

It is important to note that researchers do not make things up as they go along! Whilst flexibility has advantages, unplanned changes impact on both the validity of statistical inference and the practicalities of doing the trial and may undermine the credibility of the results. The type of changes (trial adaptations), and the criteria for making them need to be considered in advance. Changing a trial part-way through needs thought. More specifically, the criteria and timing of possible adaptations are decided at the design stage and specified in trial documents (e.g., the trial protocol and statistical analysis plans). Researchers should not compromise the scientific rigour in running the trial to produce reliable and valid results to influence practice.

In summary, the overall goal of an adaptive design is to address research questions that are relevant to clinical practice quickly and efficiently while balancing ethical and scientific interests.

Figure 2.




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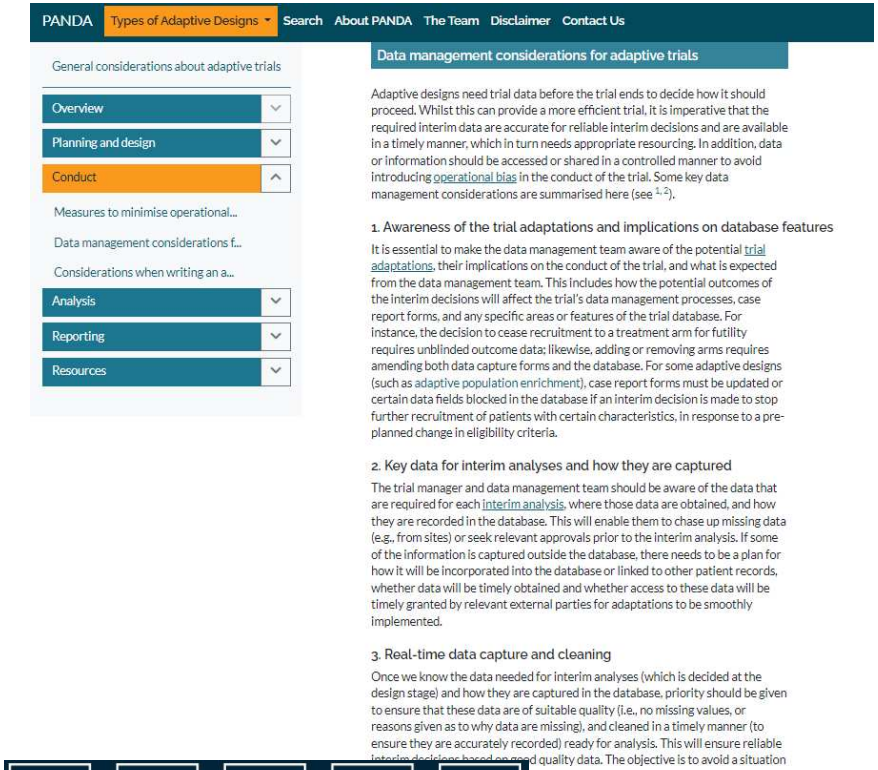
# I want to learn about general considerations …




- Specific topic (e.g., data management, costing in grant applications,
- Reporting guidance
- Resources (tutorial papers, easy-to-read books, etc)

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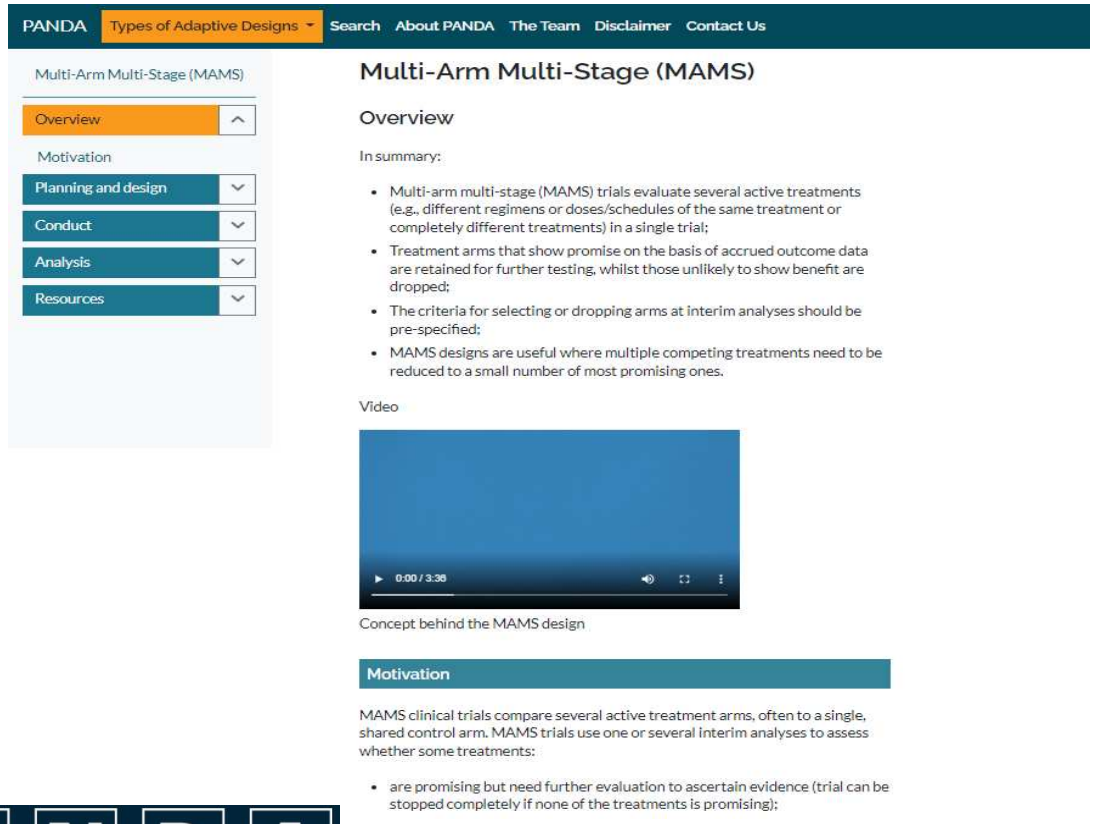
# I want to learn more about a specific adaptive design …




- Motivation
- When is it appropriate
- Design concept
- Statistical methods
- Case studies
- Statistical software
- etc

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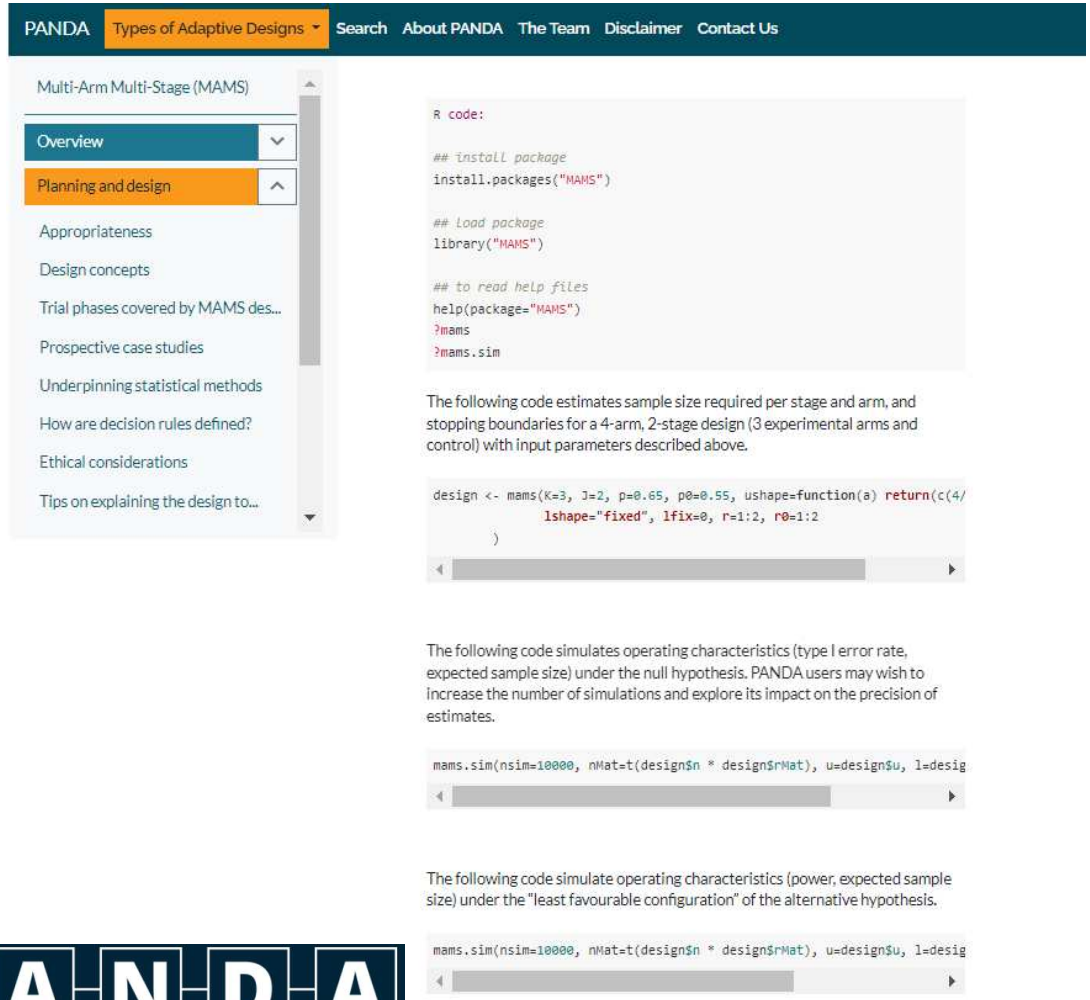
# Show me how to do it …




- **Snippets of statistical code**

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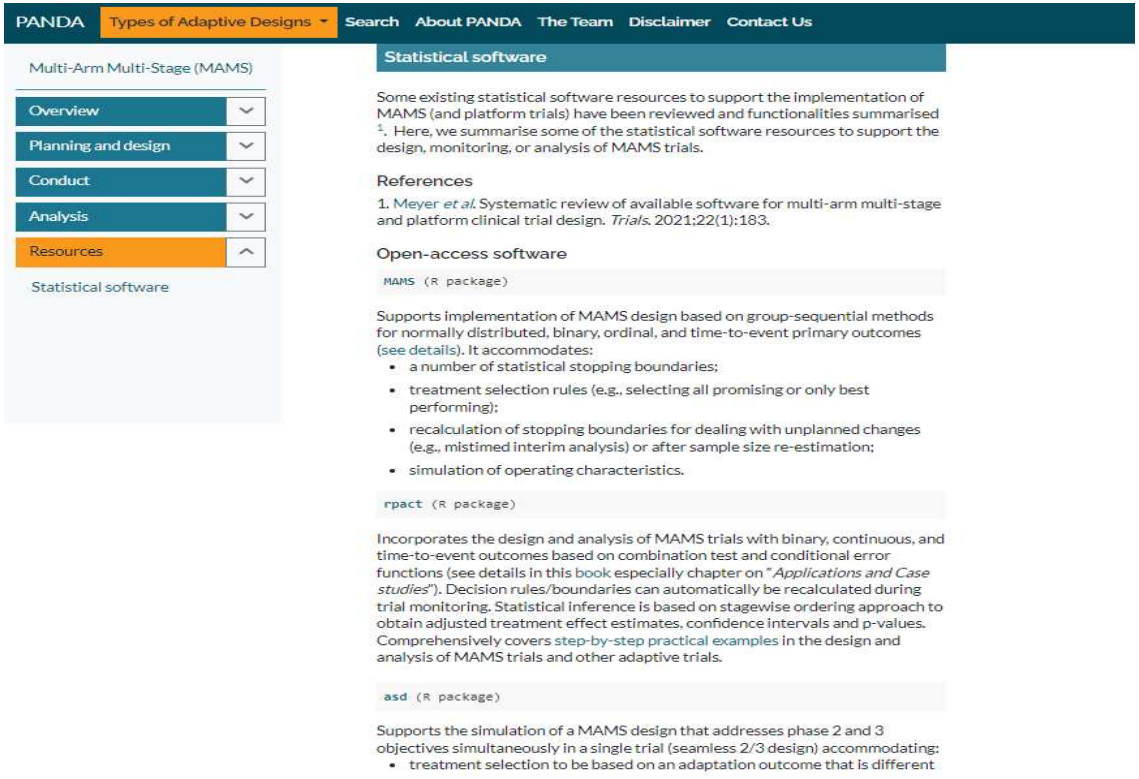
# Easy access to statistical implementation resources

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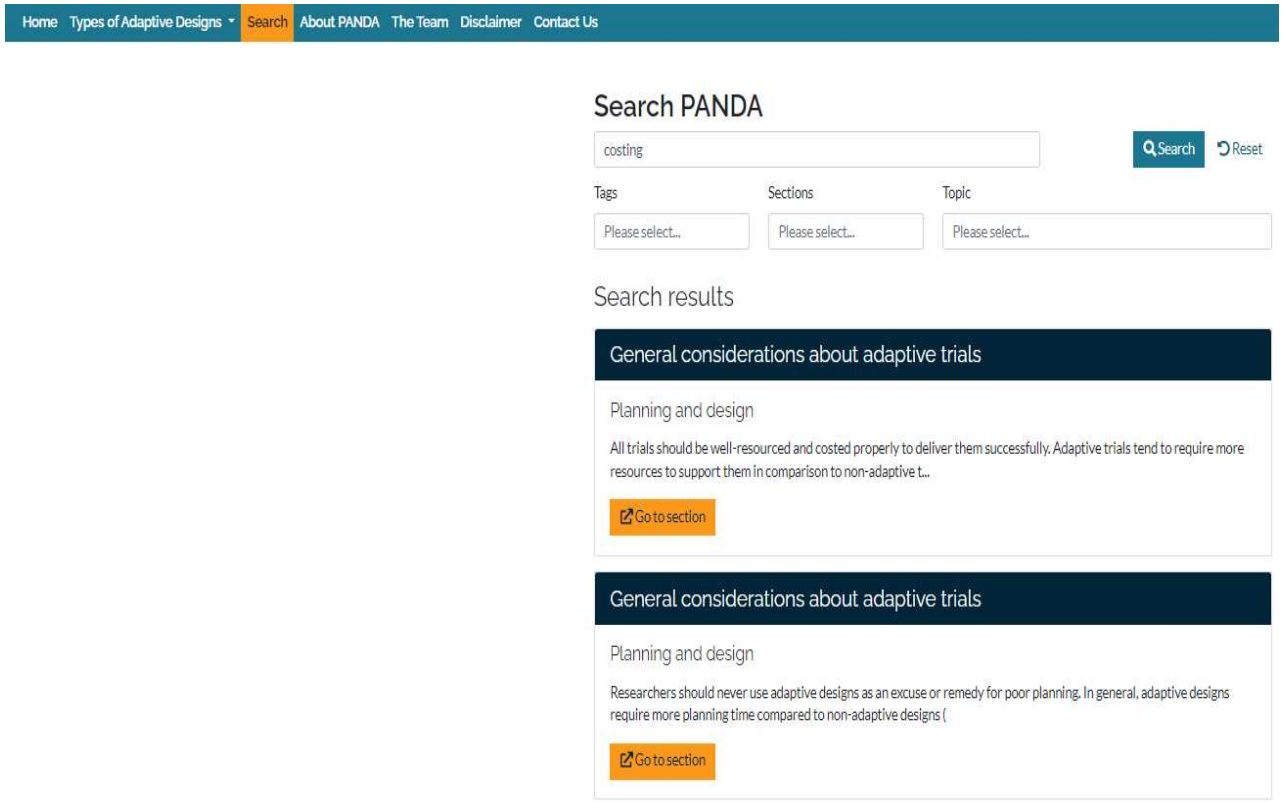
# Search facility




- Subject of interest
- In specific sections or topics
- Tag specific

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# Wishes and the future

- It is a community resource
- Work in progress (videos, content, … )
- Help us to improve the content in PANDA
  - Feedback
  - Practical related content (e.g., lessons learned from implementing adaptive trials)
- The field is growing so we need to keep PANDA up to date
  - Content relating to new adaptive designs (e.g., adaptive platform designs, etc)
- Can this be expanded to early phase trials?

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# Acknowledgements


- Funders
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- Platform developers (epiGenesys)
- ADWG
- Many people who have contributed in several ways


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# Open-access clinical trial simulation software

Alex Dmitrienko | Sep 27, 2022

# Outline

- Clinical trial simulation
- Software tool
  - R package (MedianaDesigner package)
  - Power/sample size calculations for adaptive and other trials
  - Documentation and case studies
  - Online training

# Clinical Trial Simulation

Mediana

# Clinical trial simulation

- Clinical trial simulation
  - Only reliable approach for designing modern trials with complex designs and analysis strategies
  - Simulation-based approaches free trial sponsors from artificial restrictions
- Clinical trial optimization
  - Facilitates a disciplined simulation-based evaluation of candidate trial designs to transition from traditionally used designs to optimal designs
  - *Clinical Trial Optimization Using R* (Edited by Dmitrienko and Pulkstenis, 2017)

# Open-source software tools

- Mediana package
  - R package released in 2015 to streamline the process of designing clinical trials and general research studies
  - It has become very popular in the clinical trial and general research community (downloaded over 35,000 times)
- MedianaDesigner package
  - Extended Mediana to adaptive trial designs and other trial designs

# Software Tool

Mediana

# Software tool

- Open-source software tool
  - R package (MedianaDesigner package)
- Power/sample size calculations
  - Support for simulation-based power/sample size calculations in late-stage trials, including a broad class of adaptive trials
  - User-friendly interface with emphasis on most commonly used features and design parameters
  - Efficient clinical trial simulation engine

# Two deployment options

- Desktop deployment
  - Software tool is deployed as an R package (aimed at expert users with R programming experience)
  - Available on CRAN web site
    - https://cran.r-project.org/web/packages/MedianaDesigner/index.html
- Cloud deployment
  - Software tool is available as a web application running in the cloud (aimed at beginners and casual users)
  - Web applications available on Mediana's cloud platform
    - https://cloud.mediana.us

# Power/Sample Size Calculations

Mediana

# Supported trial designs

- Adaptive designs
  - Phase II (proof-of-concept) designs
    - Response-adaptive designs
  - Phase III (confirmatory) designs
    - Adaptive designs with sample size or event count re-estimation
    - Adaptive treatment selection designs
    - Adaptive population selection designs
- Related components
  - Optimal selection of a futility stopping rule
  - Blinded event prediction in event-driven trials

# Supported trial designs

- Traditional designs
  - Traditional trials with multiple objectives
    - Support for all popular traditional multiplicity adjustments and advanced multiplicity adjustments (gatekeeping procedures)
  - Cluster-randomized trials

# Documentation and Case Studies

Mediana

# Documentation

- Technical manuals
  - Detailed description of statistical methodology with examples
    - https://mediana.us/medianadesigner/
- Online user manual
  - Multiple case studies to help users come up to speed with the software tool
    - https://medianasoft.github.io/MedianaDesigner
- English and French versions

# Online Training

Mediana

# Online training

- Ten-part training course
  - Adaptive designs and clinical trial simulation
  - Available on Mediana's YouTube channel
    - https://medianasoft.github.io/AdaptiveDesignTraining
- Introductory modules
  - First two videos (Parts 1 and 2) are aimed at a broad audience
- Technical modules
  - Remaining videos (Parts 3 through 10) are more technical and assume a statistical background

# Online training

- Adaptive designs
  - Phase II (proof-of-concept) designs: Response-adaptive designs
  - Phase III (confirmatory) designs: Designs with sample size re-estimation, treatment selection and population selection
- Methodology and case studies
  - Two videos for each class of adaptive designs
  - Underlying statistical methodology and regulatory considerations
  - Case study with a detailed software demonstration

# Summary

Mediana

# Open-access software

- Software tool
  - Open-source software tool to facilitate power/sample size calculations for traditional and adaptive trials
  - Documentation, case studies and online training
- Feedback
  - Feedback and suggestions are welcome
    - https://github.com/medianasoft/MedianaDesigner/issues

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# Thank you!

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