



PediCAP

CAPACITY BUILDING FOR PediCAP Study SITES

The Global Health Network (TGHN)

PediCAP Fourth General Assembly TC - 23rd September 2020



This project is part of the EDCTP2 programme supported by the European Union under Grant Agreement RIA2017MC - 2023

Major Achievement & Deliverables Achieved

Task 6.1

Set up online knowledge exchange hub for the Trial

Milestone 2019Q2 – 2020Q1

Task 6.2

Development of Study-specific & general research skills training programmes

Milestone 2019Q2 – 2020Q4

Task 6.1

Online Knowledge exchange Hub is live

pedicap.tghn.org

Task 6.4

Link the Study Sites with other Regional Capacity development initiatives

Milestone 2020Q3 – 2023Q4

Task 6.3

Establish PDS for Research teams that will include Capacity development

Milestone 2019 Q2 – 2023 Q4

Protocol Requirements vs Training Needs Assessment

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- 1) Protocol requirements
 - 2) Study Site requirements



Staff Training
Needs Assessment

Potential Protocol SOPs for Training

- Pedi CAP Protocol Training
- PediCAP Trial Schema
- Investigation of Site Qualification
- Participants Screening and Pre-Randomization
- Participants selection, Randomization, Treatment and F/up
- Protocol and Investigational Brochure (contents, design, amendments, and compliance)
- Study Site Master File and essential documents.
- Communication with ERC and Trial Sponsor
- Principal Investigators Qualification, Agreement and Responsibilities.
- CRFs, Source Documents, Record Keeping and Archiving
- Investigator Responsibilities
- Sponsor Responsibilities
- Informed Consent Procedures
- Receipt and Handling of Investigational Product.
- Handling and shipment of Infectious Materials.

Potential Protocol SOPs for Training

- Dosing for PediCAP.
- PediCAP Pharmacokinetic (Pk) sub study.
- PediCAP Compliance and Adherence.
- Assessing PEDICAP Efficacy.
- Assessing PEDICAP Safety.
- Adverse Events Identification and Reporting.
- Data Sharing and Access Plan.
- Trial Monitoring Plan.
- Biological Sample Sharing.
- Sample Shipment.
- Sample Algorithm.
- PK sampling and Analysis.
- Microbiological Sampling and Analysis.
- Pediatric Phlebotomy Training.
- Performing C-Reactive Protein.
- Hospital Hygiene and Infectious Control.
- SOP Identification and Development

Milestone April- Sept 2020

WP6 Capacity Building & Networking

TASK 6.2 Study Specific

- APRIL 9: PediCAP WP6 Deliverable meet
- APRIL 16: WP6 Team meeting
- APRIL 24: Pedicap WP6 meeting

JUNE 5: Contacted All Site Coordinators: AHRI, MU, CHSUZ, CHBAH, UTH-Zambia
JUNE 6: MRC/TGHN: WP6 & Training platform.
JUNE17: PediCAP Consortium

eLearning Materials under development

- ✓ PediCAP Protocol
- ✓ Childhood Pneumonia

SEPT 21: Pedi CAP WP6 Catchup



- MAY 7: PDS Support Toolkit
- MAY 12: PDS Moderation Training
- MAY 13: PDS development & Usage
- MAY 14: PDS SOP review

JUN20: PDS Moderation Catchup

AUG 24: PDS Moderation w/shop

- PDS Tools ready
- ✓ Animation for demo
- ✓ Simple Guide
- ✓ Moderation Team

Jun15: PDS Moderation & Dashboard

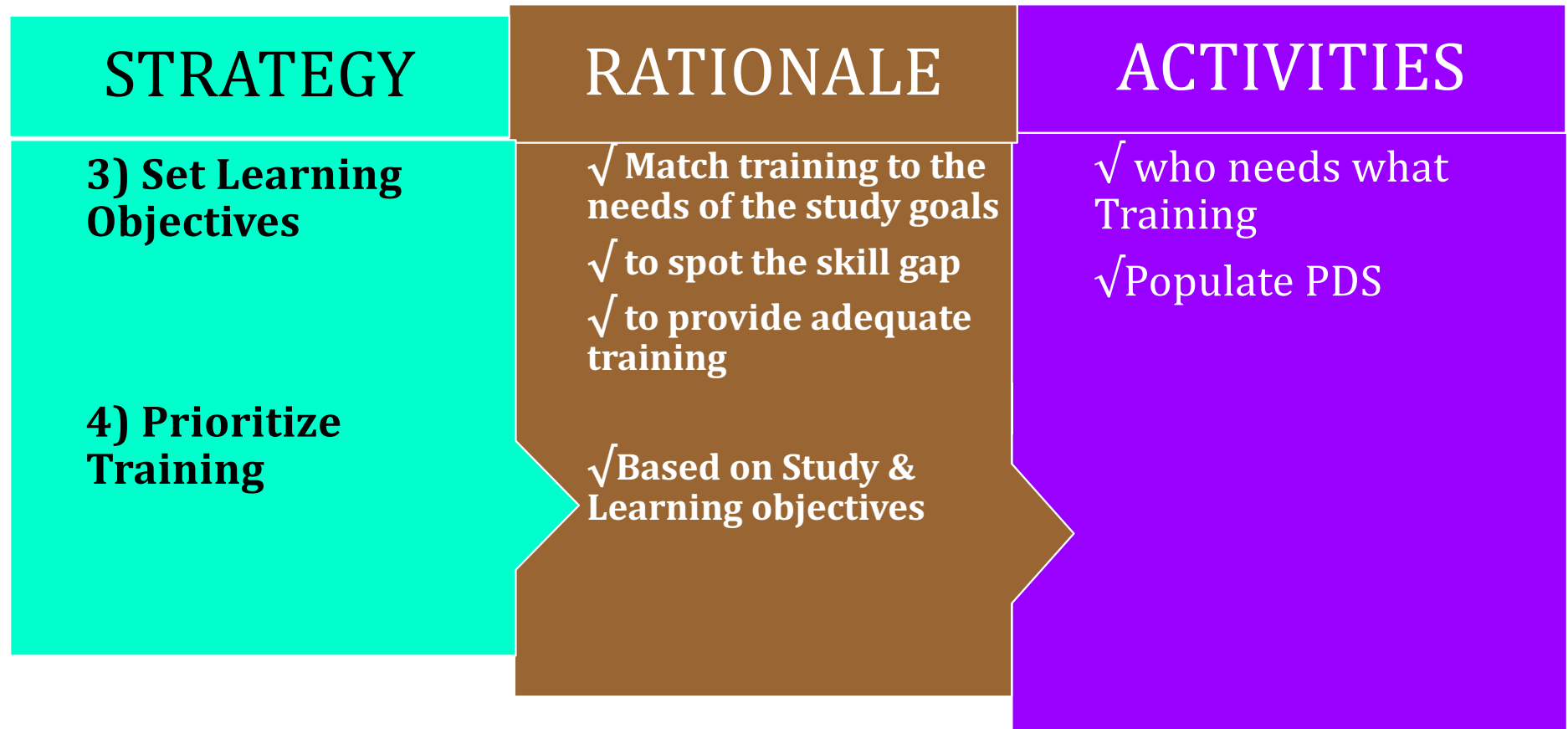
Jun29: PDS Moderation Catchup

TASK 6.3 PDS tool development

Q4 2020 TASK 6.2 (TRAINING NEEDS ASSESSMENT)

STRATEGY	RATIONALE	ACTIVITIES
<p>1) Involve the Site Study Coordinators</p> <p>2) Involve the Site Study Staff</p>	<p>√ They understand the need of the site.</p> <p>√ Make staff own the Training process.</p>	<p>√ Design survey questionnaire for staff.</p> <p>√ Review Site Organogram.</p> <p>√ Review Roles & Responsibilities - JD</p> <p>√ Break down & articulates what staff needs to know, understand & able to do.</p>

Q4 2020 TASK 6.2 (TRAINING NEEDS ASSESSMENT)



Q4 2020 TASK 6.2 (TRAINING NEEDS ASSESSMENT)

STRATEGY	RATIONALE	ACTIVITIES
<p>5) Design & Conduct Training Program</p> <p>6) Evaluate Training</p>	<p>√ Break down & articulate what staff needs to know, understand & able to do</p> <p>√ What needs fine-tuning or scrapping off.</p> <p>√ What Training resources are needed.</p>	<p>√ Face-to-Face Workshops</p> <p>√ eLearning</p> <p>√ Live Webinars</p> <p>√ Track Learning/Training</p> <p>√ Conduct survey after every training/workshop.</p> <p>√ Track Capacity Development</p> <p>√ Impact Assessment</p>

Task 6.4: Linking Study Sites with other Regional Capacity

