How can we rapidly and efficiently optimize the best therapeutic management for COVID-19?

REMAP-CAP (Nepal)

JICA COVID-19 Webinar Series
8th webinar, 21st Oct 2021

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NICRF AND NEPAL ICU REGISTRY

Outline

1. Challenges and barriers to implementing research projects in LMIC
2. Need for research capacity building in Nepal and role of CCAA
3. Implementaion of REMAP-CAP in Nepal
4. Utilization of ICU Registry for REMAP-CAP
5. How to strengthen ICU Registry and registry- based trials
6. Contributions to scientific evidence generation in global platform
7. How CCAA is representing LMICs globally?

Challenges and barriers to implementing research projects in LMIC

- Awareness of health research and clinical trials
- Motivation to lead or work on clinical trials
- Knowledge and technical skills to undertake trials
- Trial leadership capabilities
- Logistics, research relevancy and implementation issues
- Paucity of facilities, trained human resources, expertise, capacity building
- Lack of funding sources
- Lack of patient education and support

BMJ Open 2017;**7:**e017246

Need for research capacity building in Nepal and role of CCAA

- Wellcome- Oxford Innovations Flagship project "Collaboration for Research, Implementation and Training in Critical care in Asia-Africa" (CRIT Care Asia- Africa)

- Cloud-based CCA registry platform, spanning nine Asian countries

- Nepal Intensive Care Research Foundation and Nepal ICU Registry

CRIT CARE ASIA

Collaboration for Research, Implementation & Training in intensive CARE in ASIA

NICRF and Nepal ICU Registry

- NICRF hosts the Nepal ICU Registry

- Aims to support healthcare teams to build a network of healthcare facilities who work together as a Community of Practice to improve quality of critical care and enable high quality multi centre clinical research.

Nepal

REMAP CAP IMPLEMENTATION

ICU registry

REMAP RMC
NATIONAL PI
LOCAL
RESEARCH
TEAM

Remote site onboarding

Embedded in Registry

Implementation

Sites

1. Nepal Mediciti
2. Grande International Hospital
3. HAMS
4. Tribhuvan University Teaching Hospital
5. Chitwan Medical College

Roles and Responsibilities of Research Team

Principal Investigator

- National IRB review and approval
- Ensure Protocol compliance
- Adverse event and protocol deviation reporting
- Site visit monitoring reporting
- Adhere to country law and regulation to protect the rights and safety of the patients enrolled

Site Investigator

- Site IRB review and approval
- Coordinate with consultants about the study
- Key person to monitor the patient safety in specific site
- Responsible to make study related decision, make medical judgement and study subjects regarding decisions

CCA Regional Coordinator

- Overall support and guidance
- Translating study protocol in practical SOP's
- Simplifying complexities of REMAP process
- Data quality check and data extraction
- Central monitoring

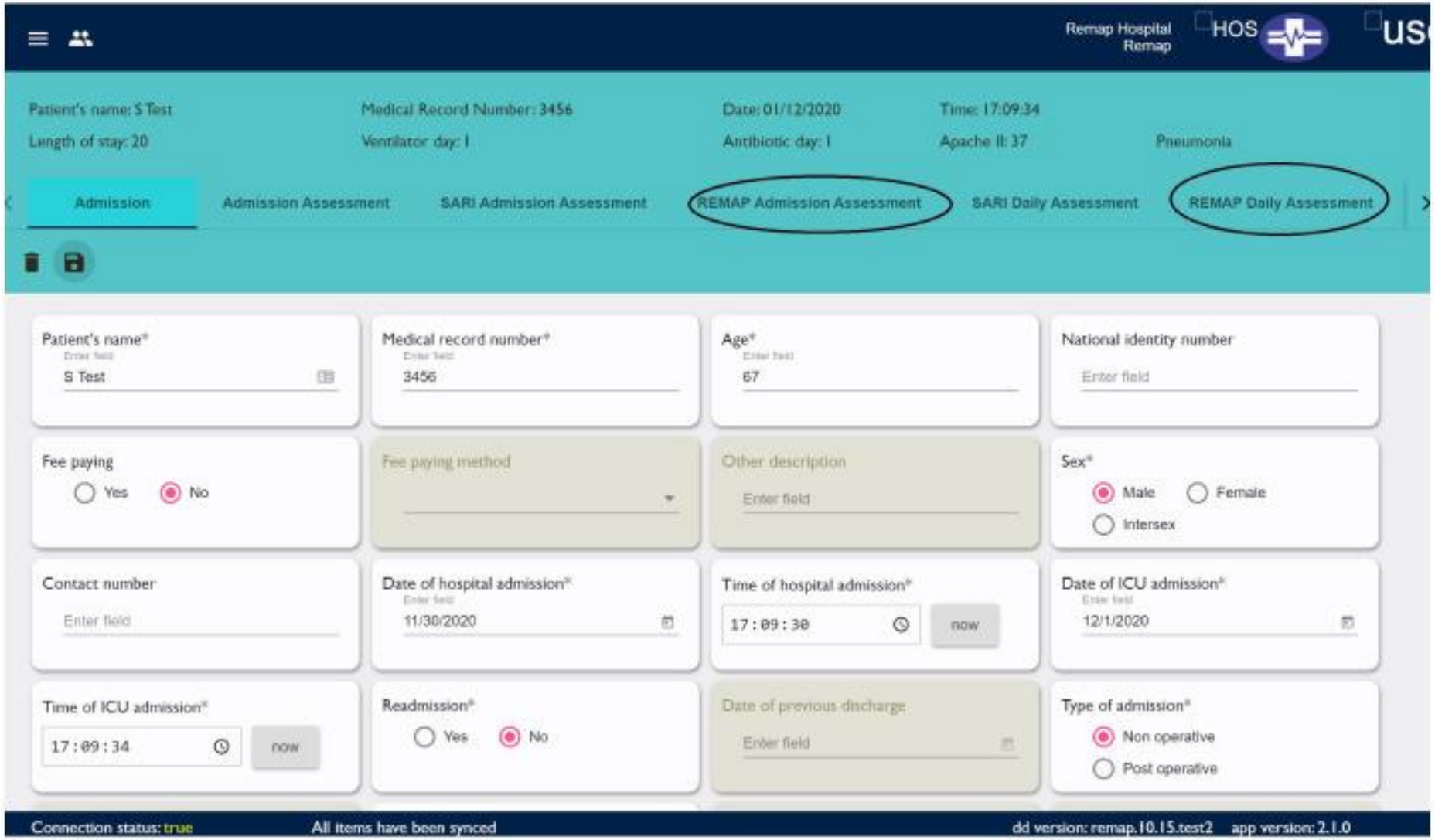
National Coordinator

- Coordinate with all team members
- Data quality check
- Collect consent form and upload in shared drive
- Monitor trial to ensure compliance at site level
- Conduct training and site visit monitoring

Site Research Coordinator

- Screening, randomization enrollment
- Daily data entry
- Consent taking
- Proper reporting of adverse event

Integration of the REMAP Case Report Forms (CRF) into the ICU registry



REMAP Trial Process

Screening

- Research coordinator at each site use monitoring sheet and screen all patients admitted to COVID ICU (suspected or confirmed) to identify the eligible patients for REMAP

Consent Taking

- Research coordinator approach to the patients/relatives and take written consent to enroll the patients in REMAP. Research coordinator captures the consent information in registry

Randomization

- Patients who give consent are randomized using spinnaker website to therapeutic or routine care. Trial ID is generated from spinnaker which is used to fill the REMAP Admission assessment form. Intervention is mentioned in the REMAP Medication Administration Form followed by other medication used during the treatment. Intervention is informed to ICU consultant.

Data Entry

- Daily data entry is done in registry. Daily data entry includes SARI Daily Assessment Form and REMAP Daily Assessment Form. On ICU discharge, SARI Pre-Discharge Form and REMAP ICU Discharge Form is filled. On hospital discharge, REMAP Hospital Discharge Form is filled.

Team building : Community of Practice

- Engage and inspire through mentorship
- Involve local staff
- Ownership and empowerment of local staff (RMC)
- Dedicated time for research work
- Financial incentives and salaried time for research
- Research linked to career progression
- Use global network for support

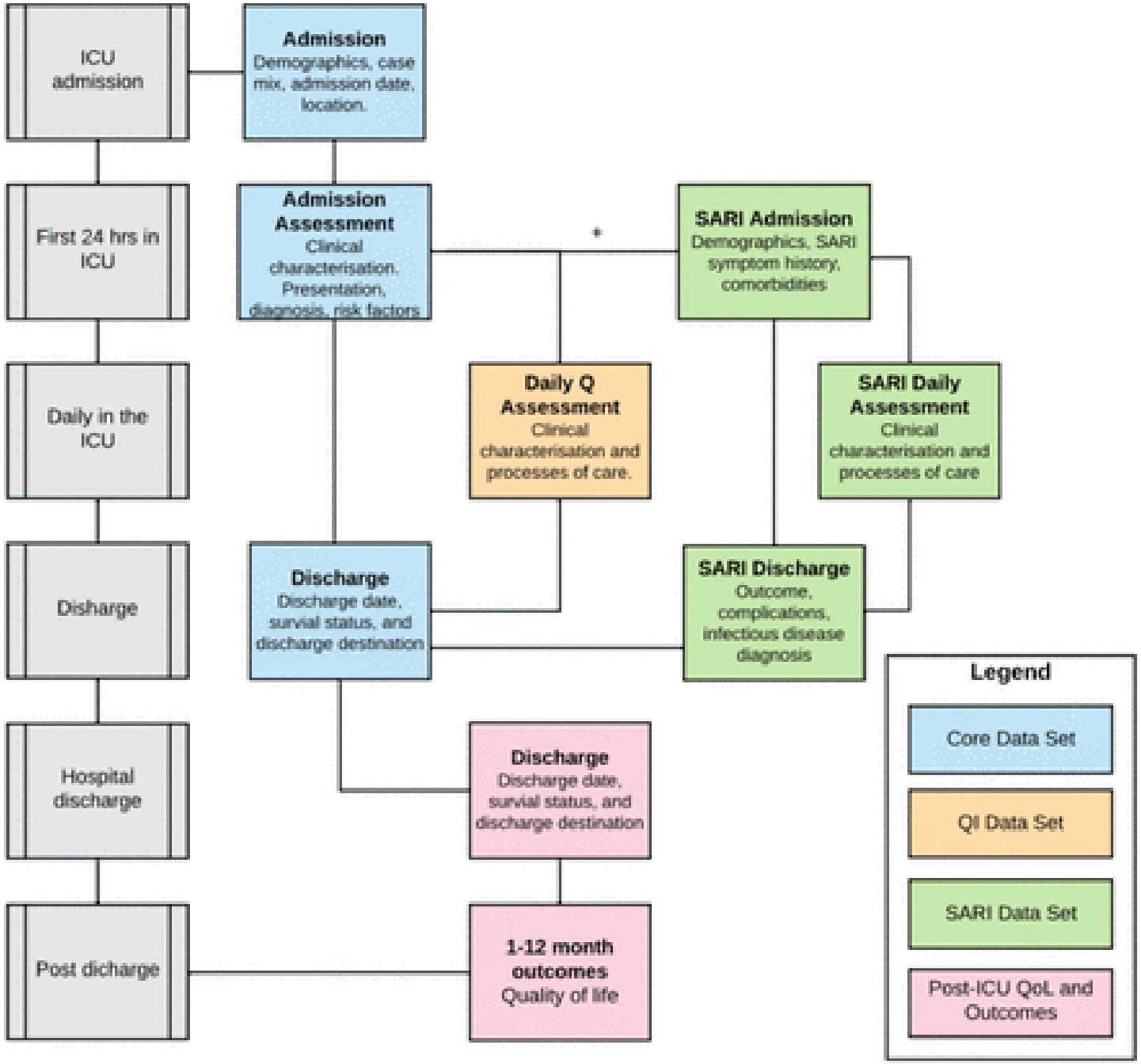
Capacity Building - Progress

- Dedicated Research Officers and Research Coordinators
- Trained site-specific coordinators, research nurses and data collectors
- PhD projects on context specific issues
- Trainings
- Development of technical skills
- Incentivisation models

How to strengthen ICU Registry and registry- based trials

- The availability of high-quality data systems to inform delivery, evaluation and improvement of health care
- Investment in systems which provide data to drive research and improvement
- Example: Use of Directory of Clinical Databases (DoCDat) framework for data quality assurance

CRIT CARE ASIA
registries modular data structure



medRxiv 2021.07.10.21260243; doi: https://doi.org/10.1101/2021.07.10.21260243

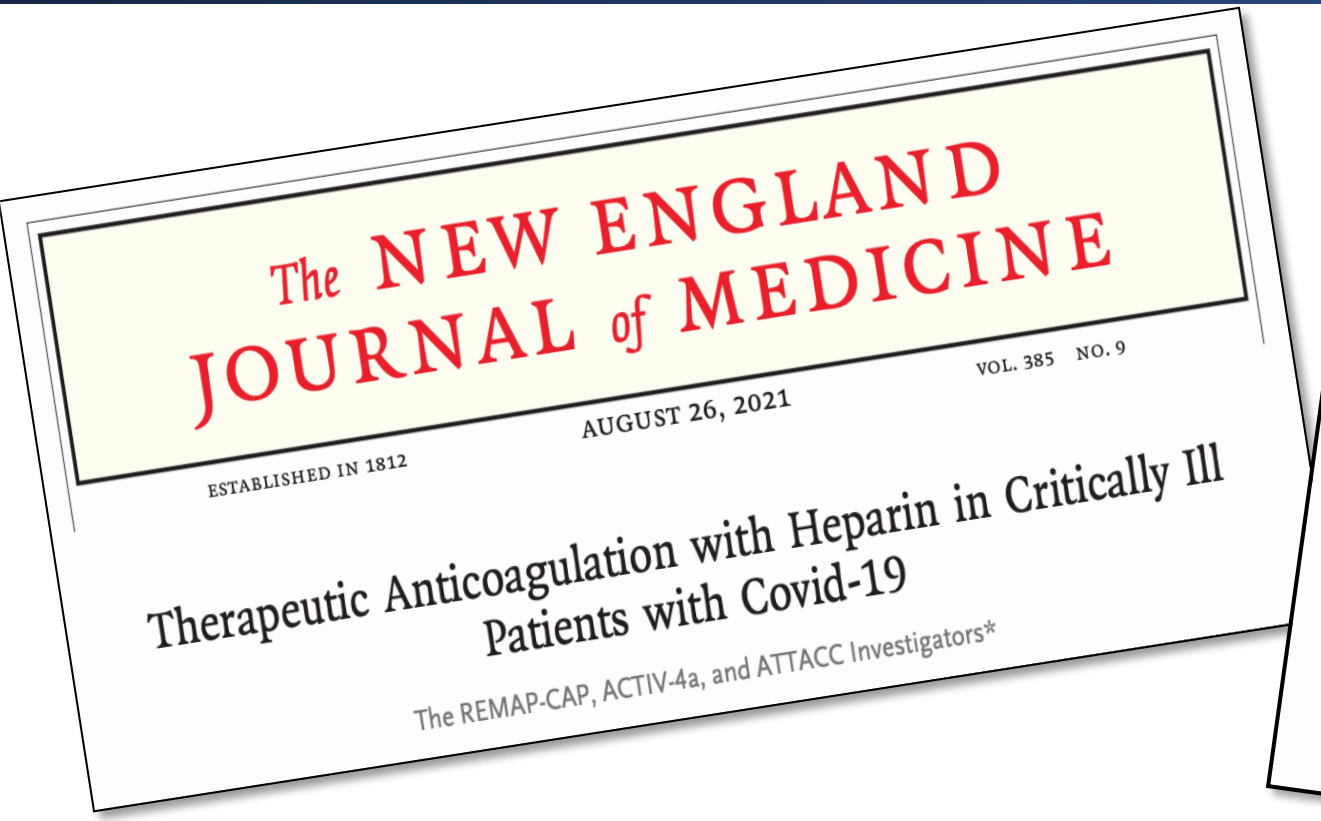
A summary of the performance of the registries using the DoCDat criteria

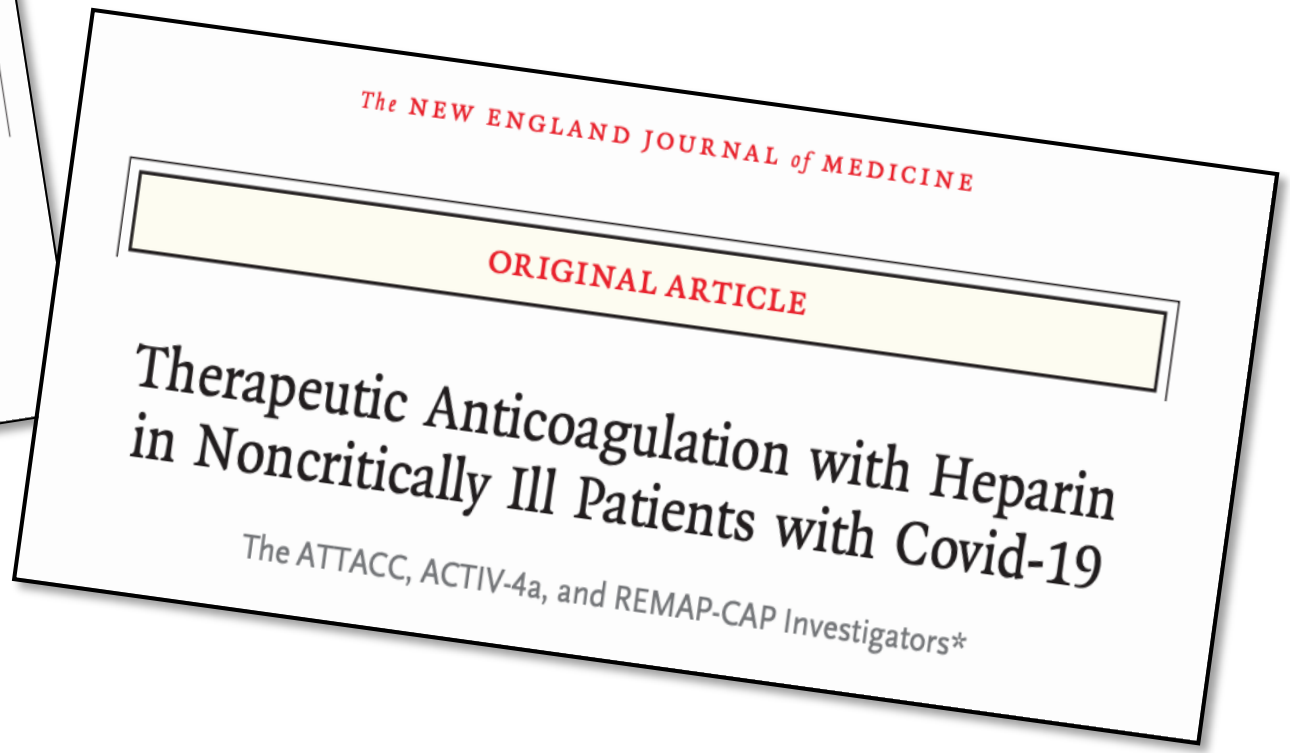
	Crit Care Asia registries score#		DoCDat database*
A. Representativeness of country	1.5 (1-2)	■ ■ ■ ■	3 (2-4)
B.Completeness of recruitment	2.7 (2-3)	■ ■ ■ ■	3 (1-4)
C. Variables included	3.3 (3-4)	■ ■ ■ ■	3 (2-4)
D. Completeness of data	3.8 (3-4)	■ ■ ■ ■	2 (1-3)
E. Collection of raw data	3.8 (3-4)	■ ■ ■ ■	4 (4-4)
F. Explicit definitions	4 (4-4)	■ ■ ■ ■	2 (1-4)
G. Explicit rules	3.8 (3-4)	■ ■ ■ ■	3 (1-4)
H. Reliability of coding	3.7 (2-4)	■ ■ ■ ■	1 (1-4)
I. Independence of observations	3.8 (3-4)	■ ■ ■ ■	4 (2-4)
J. Data validation	3.5 (3-4)	■ ■ ■ ■	3 (3-4)

Average score of 6 independent reviewers, displayed as average (minimum and maximum scores attributed by individual scorers).

*Extracted from reference [11]

Contributions to scientific evidence generation in global platform





How CCAA is representing LMICs globally?

- Collabration with global research community
- Represent LMICs in ITSCs of multi centre global trials
- Co-ownership of LMIC reserachers in global multicentre research works

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Thank you

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CRIT CARE AFRICA

REMAP-CAP

NEPAL INTENSIVE CARE RESEARCH FOUNDATION