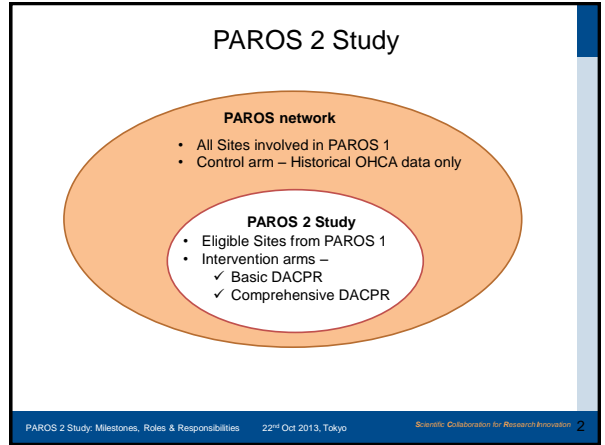**PAROS 2 Study:**
Milestones, Roles &
Responsibilities

Nurun Nisa de Souza
Epidemiologist
Singapore Clinical Research Institute

PAROS 2 Study: Milestones, Roles & Responsibilities   22nd Oct 2013, Tokyo   *Scientific Collaboration for Research Innovation*
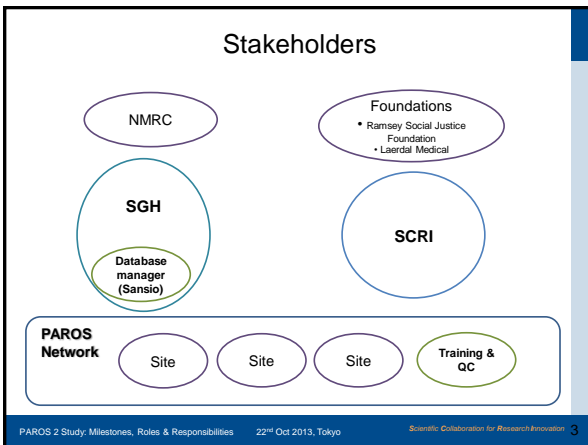

PAROS 2 Study

PAROS network
- All Sites involved in PAROS 1
- Control arm – Historical OHCA data only

PAROS 2 Study
- Eligible Sites from PAROS 1
- Intervention arms –
  - ✓ Basic DACPR
  - ✓ Comprehensive DACPR

PAROS 2 Study: Milestones, Roles & Responsibilities   22nd Oct 2013, Tokyo   *Scientific Collaboration for Research Innovation* 2

Stakeholders

NMRC

Foundations
- Ramsey Social Justice Foundation
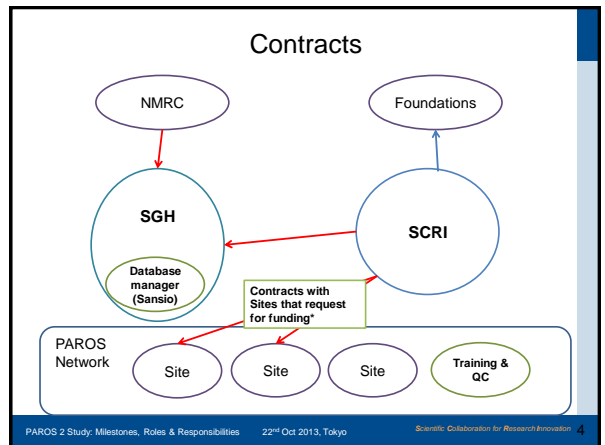- Laerdal Medical

SGH

SCRI

Database manager (Sansio)

PAROS Network

Site   Site   Site   **Training & QC**

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Contracts

NMRC

Foundations

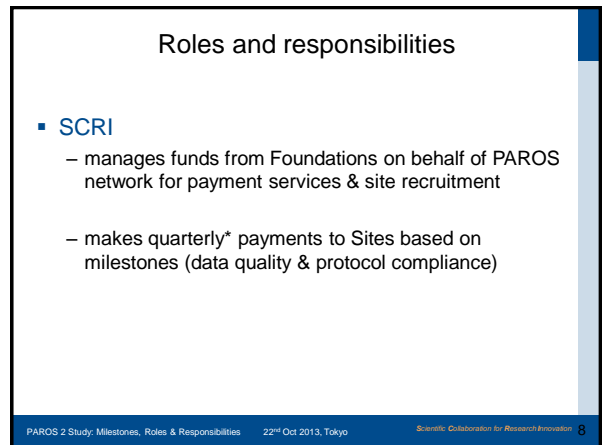**SGH**
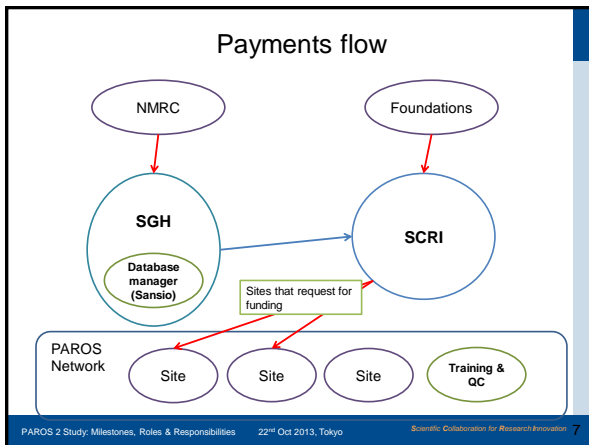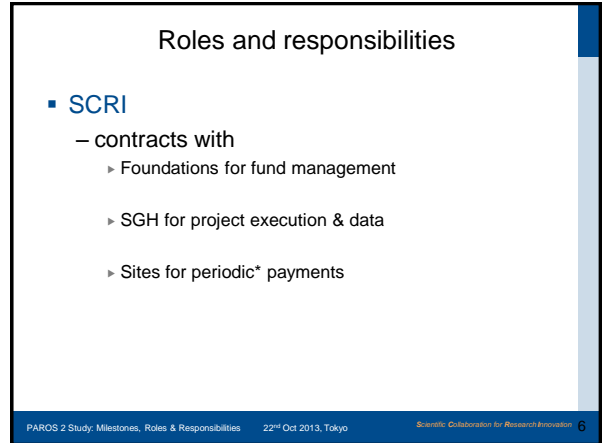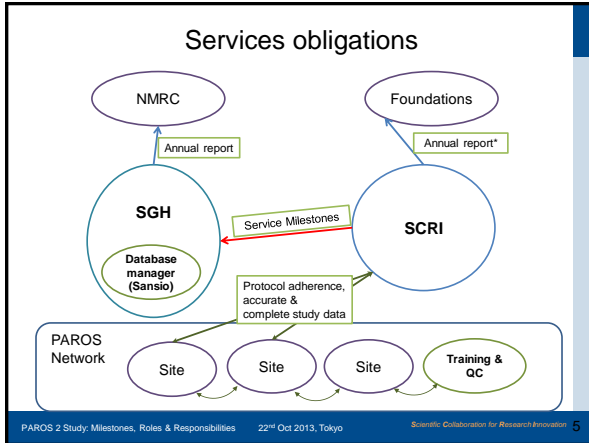
SCRI

Database manager (Sansio)

Contracts with Sites that request for funding*

PAROS Network

Site   Site   Site   **Training & QC**

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Services obligations

Roles and responsibilities

- SCRI
  - contracts with
    - Foundations for fund management
    - SGH for project execution & data
    - Sites for periodic* payments

Payments flow

Roles and responsibilities

- SCRI
  - manages funds from Foundations on behalf of PAROS network for payment services & site recruitment
  - makes quarterly* payments to Sites based on milestones (data quality & protocol compliance)

Site Payment Milestones

Domain	Site Load	Cutoff	Comments	Item on ePAROS
Missing data	**>500**	**0.5%**	**All core variables**	
- Core variables	**≤ 500**	**1.0%**		
Compliance	**>500**	• **>80% of calls where DACPR was offered**	**Excluding non-CA calls and the calls where CPR has already been started**	**CPR instructions started?**
	≤ 500	• **Maintain >80% of trained total dispatchers at any one time**		
Out-of-range	**>500**	**<5%**	**All core variables that are amenable to range**	
- Core variables	**≤ 500**	**<1%**		
Inconsistence	**>500**	**<5%**	**All core time variables that can be linked to earliest recorded time**	
- Core variables	**≤ 500**	**<1%**		

Recommendations for participation

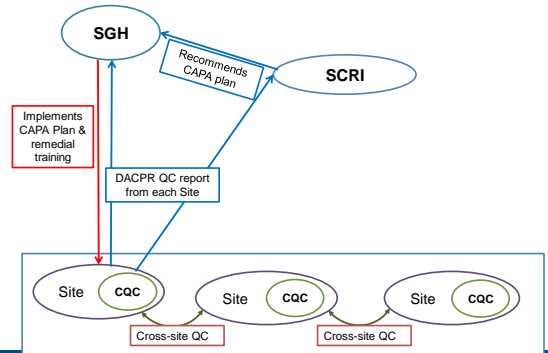| Site responsibilities	Comments
Have ≥6 months of historical run-in data (OHCA & bystander CPR)	Eligibility
ePAROS sites - Enter data from EMS, hospital & call center	Date of last data entry no later than 3 months
PAROS sites - Send EMS & hospital data in Excel sheets; enter call center data into ePAROS	
Sites to respond to data queries from SGH in a timely manner	All queries resolved before next quarterly report*
Sites assigned to comprehensive level DA-CPR intervention type are: - to use a quality measurement tool and - commit to Quality Improvement Program and Community Education Program.	As agreed by PAROS network

Data flow
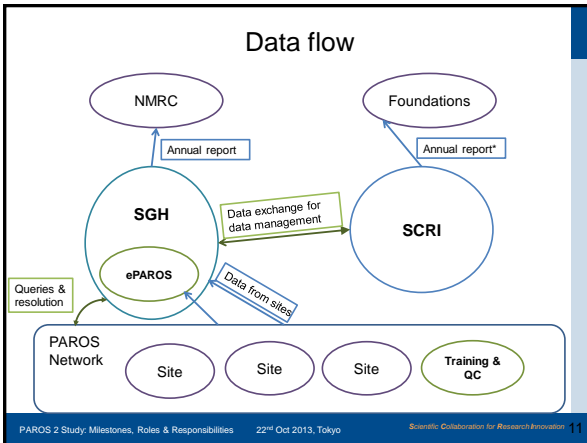
Roles and responsibilities

- Sites
  - regularly enter data from call centers, EMS and hospitals into e-PAROS database
  - respond to data queries from SGH in a timely manner
  - comply with the protocol & remedial training
- Database manager
  - maintain e-PAROS database
  - submit quarterly data quality control (DQC) reports – missing fields, inconsistencies, out-of-range to PAROS 2 Data Management (DM) team (Susan)*

Roles and responsibilities (cont.)

- SCRI
  - supports SGH DM team to maintain data quality
  - Submits quarterly QC reports for site payment authorization by SGH
  - final data analyses
- SGH
  - manages, cleans and queries incoming data
  - corresponds with Sites to resolve data queries
  - sends data to SCRI for merging process and responds to data queries

Call QC of DACPR process

Roles and responsibilities

- Sites (monthly?)
  - Conduct periodic cross-site audit for DACPR QC
  - Auditors submit DACPR QC report to SCRI & SGH
  - Implement Corrective Action Preventive Action (CAPA) Plan & carry out remedial training
- SGH
  - Reviews DACPR QC reports from Sites
  - Outlines CAPA plan based on SCRI's recommendations
- SCRI
  - Receives DACPR QC reports
  - Makes recommendations for CAPA plan to SGH

Other matters for discussion

- Sites that require funds & criteria to qualify for funds
- Quarterly reports
  - Quality of data & DACPR call review
  - Indicators for call quality
  - Feasibility
- Periodic reports to Foundations
  - Information to include (financial summary, study progress, etc)
- AOB