DATA QUALITY ASSURANCE PLAN FOR PAN-ASIAN RESUSCITATION OUTCOMES STUDY (PAROS)

1. Purpose and Scope

1.1. The purpose of the data quality assurance plan is to ensure that data contributed to the PAROS study is done so in the manner as recommended in this document to uphold data integrity.

1.2. This document defines the roles and responsibilities of the various parties involved in the process, procedures for quality checks/activities (to ensure accuracy and completeness of data), and the recommended timelines that would apply. It is to be conducted in compliance to the protocol, applicable SOPs, GCP, IRB and Regulatory Authority requirements. This plan is not intended to be a static document; change as conditions warrant must be documented and approved by the EXCO and/or the PAROS Clinical Research Network (CRN) Chairman.

2. Roles, Responsibilities, and Quality Control Activities of Data Personnel Involved

2.1. There are three broad categories of data personnel:

a. (International) study level: *Study Data Administrator*
b. Regional or country level: *Regional/Country Data Administrator*
c. Site level: *Site Data Administrator*

Depending on the data model of the country, the three categories are not mutually exclusive. For example, Regional/Country Data Administrators can also be Site Data Administrator.

2.2. The following table shows the roles and responsibilities of the data administrators, and their Quality Control (QC) activities:

DATA ADMINISTRATOR TYPE	ROLES & RESPONSIBILITIES	QUALITY CONTROL ACTIVITIES
(International) study level: *Study Data Administrator*	a. Request for a copy of approvals and related information b. Issue ePAROS access to data personnel at the site, regional, and country level c. Conduct training on the ePAROS system d. Liaise with server provider on any systemic change to ePAROS e. Clarify queries with other data administrators f. Carry out for-cause investigations g. Work with the Regional/Country Data Administrators for data recoding and migration (if applicable)	a. Maintain Quality Control log (Annex A) for issues identified and/or rectified by Study Data Personnel b. Perform logical and consistency checks (e.g. using range and field type checks)
Regional or country level: *Regional/Country Data Administrator*	a. Provide prompt responses (within two working weeks) to Study Data Administrator upon request for information or clarification b. Clarify queries with other data administrators (site, study) c. Maintain a copy of valid approval from the ethics review board (or equivalent) for the country or region d. Report regional or country-wide accrual rate when requested by Study Data Administrator e. Report any deviation from protocol involving data entered into ePAROS f. Work with the other data administrators to resolve corrections or issues in a timely manner g. Be trained in using ePAROS (if applicable)	a. Maintain Quality Control log for issues identified and/or rectified by Regional/Country Data Administrator b. Ensure correctly matched cases based on identifiers (if applicable) c. Ensure correctly translated fields in the data collection form as validated by back translation (if applicable) d. Ensure that validated data collection form is uniformly applied throughout the participating region and country k. Ensure that data from a region or country is accurate, complete and

DATA ADMINISTRATOR TYPE	ROLES & RESPONSIBILITIES	QUALITY CONTROL ACTIVITIES
	h. Assist in the training of users using the ePAROS (if applicable) i. Ensure that data to be migrated is accurate, complete and correctly mapped (if applicable) j. Work with the Study Data Administrator for data recoding and migration (if applicable)	provided/entered in accordance to recommended timelines (see Section 4) e. Perform logical and consistency checks (e.g. using range and field type checks)
Site level: *Site Data Administrator*	a. Provide prompt responses (within one working week) to other data administrators upon request for information or clarification b. Clarify data queries with other data administrators l. Maintain a copy of valid approval from the ethics review board (or equivalent) for the site c. Report accrual rate at site when requested by Region/Country and Study Data Administrator d. Report any deviation from protocol involving data entered into ePAROS e. Work with the other data administrators to resolve corrections or issues in accordance to recommended timelines (see Section 4) f. Attend training of the ePAROS system as and when required (if applicable) g. Work with the Regional/Country Data Administrator for data recoding and migration (if applicable)	a. Maintain Quality Control log for issues identified and/or rectified by Site Data Administrator b. Ensure correctly matched cases based on identifiers (if applicable) c. Ensure correctly translated fields (if applicable) d. Ensure that data from site is accurate, complete and provided/entered in accordance to recommended timelines (see Section 4) e. Perform logical and consistency checks (e.g. using range and field type checks) h. Ensure that data transcribed from source documents to (paper) data collection form is accurate and complete (if applicable)

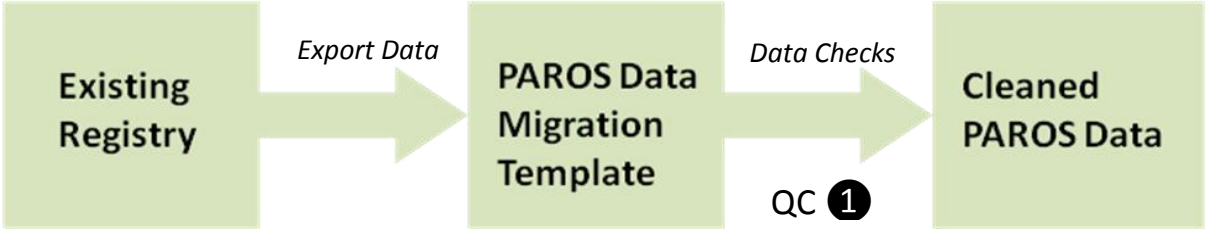
3. Data Flow and Quality Control Processes

3.1. The data flows for the two methods of contributing data to PAROS are as follows:

Direct Entry Online (ePAROS)

QC ❶: Site performs QC on ePAROS data against source data
QC ❷: Logic Data checks on ePAROS data by Regional/Country and/or Study Data Administrator

Export Field Entry



QC ❶: Logic Data checks exported data by Regional/Country and/or Study Data Administrator

3.2. The following table articulates the data checks applicable to the two methods of data contribution:

TYPE OF DATA CHECKS	DESCRIPTION	FREQUENCY
Direct Entry Online		
Computer checks in ePAROS	Entered data will be subjected to systemic validation rules	When entering data into ePAROS
Logic data checks	Checks will be on all data fields entered for a particular case (see Annex B)	Logic data checks performed at the site or region level should be done within 2 calendar months from incident date of case. On the study level, a frequency table will be worked out with the Study Data Administrator
Export Field Entry		
Logic data checks	Checks will be on all data fields migrated onto the data migration template (jointly worked out with the Study Data Administrator). Reference can be taken from the logic data checks using the Direct Entry Online method (see Annex B)	Frequency of check by Study Data Administrator on the fields selected for checking depends on the frequency of batch transfer worked out with the individual country or region

3.3. Where a data query is made (by the verifying personnel or any other authorised persons to the data), the data query should be documented in the log which should be maintained at the site, and at any other applicable levels (e.g. region/country or study if the query came from outside that site) (see Annex A).

3.4. All Quality Control logs should be maintained at each site, region and country. The Study Data Administrator can request for a copy of the Quality Control logs from sites or regions/countries on an ad-hoc or regular basis.

3.5. The site Principal Investigator (PI) will be person responsible for the data completeness and accuracy of data at the level of the site. If the site PI is not the person entering data or verifying data, it is the responsibility of the PI to work with the data personnel to be apprised of the data-related issues raised.

3.6. Where necessary, Study Data Administrator can conduct audit checks on the site/region.

4. Recommended Timelines

4.1. The following timelines are recommended for each mode of data entry:

TYPE OF DATA ENTRY	RECOMMENDED TIMELINES
Direct Entry Online (ePAROS)	Data entry: Case should be entered into ePAROS 2 calendar months from the incident date of case Data checks: Checks should be performed no more than 2 calendar weeks from the completion Resolution of data query to site: 3 work-weeks from time the query was raised Resolution of data query to region/country: 1 calendar month from

	time the query was raised
Export Field Entry	A frequency timeline for data migration will be worked out jointly with the Study Data Administrator

5. Confidentiality and Access to Data

5.1. Continuous adherence to the maintenance of privacy of the subjects, including their personal identity and all medical information is of vital importance. Personal identifiers (e.g. identification card number) should not be disclosed to unauthorised personnel.

5.2. All personnel entering data in ePAROS will be issued a username and password issued by the Study Data Administrator. Sharing of username and password is not allowed. The respective access rights to ePAROS of the three different categories of data administrator are as follows:

TYPE OF DATA ADMINISTRATOR	ACCESS RIGHTS	SYSTEMIC RIGHTS
Study Data Administrator	Access to every case entered into ePAROS study-wide	View and amend all sections
Region/Country Data Administrator	Access to every case entered into ePAROS for the said region or country	View all sections
Site Data Administrator	Access to every case entered into ePAROS for the said site	• Administrators entering EMS and Hospital data: view and amend all sections • Administrators entering EMS data only: view and amend EMS data only • Administrators entering Hospital data only: view all sections, but amend hospital data only

6. Storage and Archiving

6.1. Documents related to the study should be stored in a secured location for 7 years from date of activity (or for the applicable period required by the country, whichever longer) prior to confidential destruction.

ANNEX B

LIST OF DATA CHECKS FOR DIRECT ONLINE ENTRY METHOD

PAROS VARIABLE NO.	VARIABLE NAME	CHECK
1	Patient brought in by	When 'Own/private transport' or 'Public transport' is selected, #21 to #37 must not be filled
2	Date of incident	Should be same as or -1 day as 'Date of arrival at ED' (#38)
5	Date of birth	Format should be in Day / Month / Year (dd/mm/yyyy)
8	Medical history	When 'No' or 'Unknown' is selected, no other options can be selected
9 to 16	▪ Time call received at dispatch center (#9) ▪ Time First Responder dispatched (#10) ▪ Time Ambulance dispatched (#11) ▪ Time First Responder arrived at scene (#12) ▪ Time Ambulance arrived at scene (#13) ▪ Time EMS arrived at patient side (#14) ▪ Time Ambulance left scene (#15) ▪ Time Ambulance arrived at ED (#16)	▪ Format should be in hours: minutes: seconds (hh:mm:ss) ▪ Must not be filled if 'Non-EMS' is selected (#1)
10	Time First Responder dispatched	▪ Must not be filled if 'No First Responder dispatched' is selected ▪ #10 must be ≥ #9
11	Time Ambulance dispatched	#11 must be ≥ #9
12	Time First Responder arrived at scene	Must not be filled if 'No First Responder dispatched' is selected
13	Time Ambulance arrived at scene	#13 can be = #9 (e.g. for case found and activated by ambulance crew while returning to station)
14	Time EMS arrived at patient side	When #12 < #13, #14 can be earlier than #13
15	Time Ambulance left scene	#15 must be < #16
18	Arrest witnessed by	When 'EMS/Private Ambulance' is selected, #17 must be > #14
19	Bystander CPR	When 'Yes' is selected, 'No CPR initiated', 'First Responder' and ' Ambulance crew' must not be selected in #20
21	Bystander AED applied	When 'No' is selected in #21, ' Bystander – healthcare provider', 'Bystander – lay person' and 'Bystander – family' in #27 should not be selected
22	Resuscitation attempted by EMS/Private Ambulance	When 'No' is selected, #23 to #32 should be left blank
24 to 25	▪ Time CPR started by EMS/Private Ambulance (#24) ▪ Time AED applied by EMS/Private Ambulance	▪ When 'Not witnessed', 'Bystander – healthcare provider', 'Bystander – lay person' or 'Bystander – family' is selected in #18, #24 and #25 must be > #17 ▪ #24 and #25 must be ≥ #14

26	Prehospital Defibrillation	When 'No' is selected, 'Time of First Shock given' in #26, and #27 must not be filled
27	Defibrillation performed by	When 'Yes' is selected in #26, at least one option must be selected in #27
28	Mechanical CPR Device Used by EMS/Private Ambulance	▪ When 'No' is selected, options for 'If Yes, please specify' must not be selected ▪ When 'Yes' is selected, at least one choice should be selected from 'If Yes, please specify'
29	Prehospital advanced airway	▪ When 'No' is selected, options for 'If Yes, please specify' must not be selected ▪ When 'Yes' is selected, at least one choice should be selected from 'If Yes, please specify'
30	Prehospital drug administration	▪ When 'No' is selected, options for 'If Yes, select drugs' must not be selected ▪ When 'Yes' is selected, at least one choice should be selected from 'If Yes, select drugs'
31	Return of spontaneous circulation at scene/en-route	When 'No' is selected, options for 'If Yes, please specify' must not be selected
32	CPR discontinued at scene/en-route	▪ When 'No' is selected, options for 'If Yes, please specify' must not be selected ▪ When 'No' is selected, option ' Conveyed to ED' must be selected for #33
33	Final status at scene	▪ When 'Conveyed to ED' is selected, #34 must not be filled ▪ When ' Pronounced dead at scene' is checked, #35 to #62 must not be filled
34	Cause of arrest	When 'Trauma' is selected, options for 'If Non-trauma, please specify' must not be selected
38	Date of arrival at ED	Must be same as or +1 day from #2
39	Time of arrival at ED	Can be +/- 5min of #16 (in the situation EMS timing may not be synchronised with hospital timing). This rule is not applicable to non-EMS cases
43	Mechanical CPR device used at ED	▪ When 'No' is selected, options for 'If Yes, please specify' must not be selected ▪ When 'Yes' is selected, at least one choice should be selected from 'If Yes, please specify'
44	Advanced airway used at ED	▪ When 'No' is selected, options for 'If Yes, please specify' must not be selected ▪ When 'Yes' is selected, at least one choice should be selected from 'If Yes, please specify'
45	Drug administered at ED	▪ When 'No' is selected, options for 'If Yes, select drug given' must not be selected ▪ When 'Yes' is selected, at least one choice should be selected from 'If Yes, select drug given'
46	Return of spontaneous circulation at ED	When 'No' is selected, options for 'If Yes, please specify' must not be selected
51	Cause of arrest	When 'Trauma' is selected, options for 'If Non-trauma, please specify' must not be selected

53	Outcome of patient	When 'Died in ED' or 'Unknown' is selected, #54 to #62 must not be selected
54	Patient status	▪ When 'Remains in hospital at 30th day post arrest' is selected, #55 must not be filled ▪ When 'Died in hospital' is selected, #56 to #62 must not be filled
56	Patient neurological status on discharge or at 30th day post arrest	When 'Unknown' is selected, ' Cerebral Performance Category' and 'Overall Performance Category' in #56, and #57 to #62 must not be filled