COMPUTER SYSTEM VALIDATION
RISK ASSESSMENT TOOL
SAMPLE

1. System details:

System name:	
System:	EDGE Clinical Management System
Manufacturer/vendor:	Clinical Informatics Research Unit University of South Hampton
Software and version:	Version 2.0
Principal User:	Alberta Clinical Research Consortium
Location of the system:	Web-accessible, data is stored at Q9 networks located in Ontario
Outline of system attributes:	Project level main attributes include: Owned by, Short Title, Full Title, Summary, Status, Visibility, Phase, Randomization, Project Type, Type of Trial, Study Chair, Planned Portfolio Start Date, Planned Portfolio Exit Date, Portfolio Exit Date, Disease Area, Patient workflow, Patient Data Collection Plan, Patient Scope, Project Design, Inclusion/Exclusion Criteria, Funders/Sponsors, Project Support, EDGE ID, Local Project Reference, EudraCT, WHO, ISRCTN, Clinical Trials Gov, Protocol ID, Gender, Age Requirements, Target Size and Length of Follow-up (months). This System Validation does not include organization-customized fields which are to be tested by the Site Administrator (attributes). Organizational and Staff access are also available at a project level.

Section 2: Activities supported by the system

Does the system support the following activities?	**Yes or No**
Clinical studies (contains personal health information)	Yes
Non-clinical studies intended for submission to regulatory authorities	Yes
Training records or qualifications of personnel involved in performing clinical or non-clinical studies	Yes
Backup or storage of records supporting any of the above in electronic format	Yes
Transfer of records from one GxP (Good Practice) system to another	No

If the answers are all 'No', go to section 6 and tick the validation statement: 'No further action', sign off the assessment and obtain approvals. Otherwise, proceed to Section 3.

Section 3: Software category, based on the GAMP (Good Automated Manufacturing Practice) classification

GAMP classification	Tick √ one box only
GAMP 3: Commercially available, standard, non-configurable software, providing an off-the-shelf solution.	
GAMP 4: Commercially available, configurable software.	√
GAMP 5: Custom software, or customised extension to existing commercially available software (e.g. featuring macros or custom modules).	

Section 4: Regulatory risk

Impact	Document/data types generated by the system	Yes or No
High	Clinical data submitted to regulatory authorities	No
	Non-clinical data intended for submission to regulatory authorities	No
	Data featuring electronic signatures	Yes
Medium	Supporting data not intended for submission to regulatory authorities	No
	Calibration and validation records	No
Low	Records describing the planning and scheduling of regulated activities	Yes
	Monitoring records	Yes

The overall regulatory risk is the highest impact rating marked 'Yes'.

Section 5: GAMP software category/record impact matrix			
GAMP 5	Full	Full	Full
GAMP 4	Reduced	Full	Full
GAMP 3	Reduced	Reduced	Reduced
	Low impact	**Medium impact**	**High impact**

The level of validation was determined by the GAMP software category from section 3 (GAMP 4) and impact rating from section 4 (high) and in accordance with the matrix, above.

If the matrix indicates a full validation is required, tick 'Full validation' in section 6: a validation master plan (VMP) will need to be created. If the matrix indicates a reduced validation is required, tick: 'Reduced validation' in Section 6 and use the integrated validation document.

Section 6: Level of validation and approval

	Tick √ relevant box
No further action	
Reduced validation	
Full validation	√

Approver	Name	Signature	Date
Principal User			
Operations Manager			
Principal Investigator			
Quality Assurance Lead			