Checklist for Building a Smooth Relationship Between Sponsor and CRO for CDISC Standards Related Operations

Version 1.0

CDISC Team, JCROA Data Science Working Group

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[Disclaimer]
The contents of this document are based on the opinion from the CDISC Team of Data Science Working Group in JCROA (Japan CRO Association), and not the official opinion of all JCROA member companies. Please contact each CRO and confirm the details of the services.

"Compliant Process & Quality" was drawn up based on GSCPP (Points to Consider for Pharmaceutical Industries and CROs to Build and Maintain Better Collaboration; Good Sponsor-CRO Partnership Practices)[*1] by the CDISC Team, and "Prerequisites" and "Prerequisites", "DM-SDTM(EDC)", "DM-SDTM(Paper CRF)" and "Statistical Analysis" were edited by adding CDISC related items (yellow cell) to the GSCPP original checklist.

*1
http://www.jpma.or.jp/medicine/shinyaku/tiken/allotment/gscpp.html
http://www.jcroa.or.jp/outline/agreement/gscpp.html

Purpose of This Document
With the start of e-Data submission for NDA, the number of cases in which the preparation of CDISC standards compliant data is outsourced to CROs has increased. On the other hand, at present there are cases where rework and schedule delays occur sometimes due to differences in the procedures and quality standard of organizations and persons in charge at each company.

To address this situation, CDISC Team of JCROA has written up the points to consider for a smooth operation of CDISC standards related services between Sponsors and CROs, by applying the concept of quality management in GSCPP to CDISC services.
Please use this document before start of work, in order to clarify the final deliverables (services), required quality and delivery date, and use it to establish a process for effectively and efficiently creating final deliverables which meet the required quality.

How to Use This Document
Sheet "Compliant Process & Quality"
This sheet focuses on "Clarification of required quality and delivery date" and "Establishment of effective and efficient processes" from the viewpoint of quality management. The sheet can be used in various situations, but please use it especially for consensus building before the conclusion of the contract.
In addition, please refer to column F (Impacts of not executing) and column G (Remarks) which are prepared for describing the reason and intention of the check item setting, although both columns are hidden.

Please refer to the presentation materials of "Points to Consider for Effective and Efficient Quality Management of the Contracted Business on e-Data Submission" which was presented at the workshop for the persons in charge of e-Data submission (morning session II), held on October 8, 2019.

http://www.jpma.or.jp/medicine/shinyaku/tiken/symposium/

Sheets "Prerequisites", "DM-SDTM(EDC)", "DM-SDTM(Paper CRF)" and "Statistical Analysis"
First of all, please check the conditions of the outsourcing business on the "Prerequisites" sheet, and then discuss the details about overview of the services using "DM-SDTM(EDC)", "DM-SDTM(Paper CRF)" and "Statistical Analysis" sheets.

The contents of CDISC related services (yellow cell) are added in the Attachment 1 of GSCPP which intend to identify the deliverables and to clarify the roles & responsibilities on the services of Data Management and Statistical Analysis. Please use these sheets mainly for confirmation at the time of concluding a contract and/or before starting work.

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Timing	Classification	Things to do	Result	Comments about Result (free description)	Impacts of not executing	Remarks
Before concluding a contract	Clarification of required quality and delivery date	Agree on Study Data Standardization Plan (SDSP) and the contents equivalent to Attachment 8[*1]. - Standards and Dictionary versions - Data Conversion policy *1: http://www.pmda.go.jp/files/000229470.pdf	☐ Completed ☐ N/A		> Difference in the IG version from other studies in the same package may cause problem, if the same package is used.	
	Clarification of required quality and delivery date	Check the client's **required quality**, standard rules, and whether there any clinical studies to consider. - Set the required quality according to the identified risk, taking into account the difference between Critical Data and Non-critical Data.	☐ Completed ☐ N/A		> The quality standards become ambiguous, resulting in misunderstanding of the deliverables and misunderstanding of test contents and results. > There is a concern that quality may be degraded due to lack of information necessary for the deliverables. Pay special attention to legacy data conversion, as confirmation of homology with past analysis results may occur.	**Example of Required Quality (*1)** Lv.1 : No problem on the results from Pinnacle 21 Lv.2 : Meet all requirements of IG (*2) Lv.3 : Meet all requirements of IG and also sponsor's internal rules *1: Acceptable levels need to be discussed from each point of view when it is necessary to set the study level (each study protocol) risk and the system level risk (e.g. miscommunication between sponsor and CRO. etc.) separately. *2:Rework may occur, if necessary actions are not clarified in advance since there is a big gap between "No problem on the results from Pinnacle 21" and "Meet all requirements of IG". It is necessary to decide whether to implement it on the sponsor's or the CRO's criteria, because the outputs may be different between sponsor and CRO depending on the interpretation of IG.
	Establishment of Process	Determine **stakeholders** and share them in both companies. - Decision-maker and Approver - Person in charge of quality control for each deliverable - Others	☐ Completed ☐ N/A		> The impact on the schedule is a concern when decisions and approvals are made in overseas department, such as in the case of foreign-affiliated companies. > Quality management of data (converted and conversion source data of SDTM, and ADaM) becomes ambiguous. > Recognition errors after data collection may occur, if the contents of CRF are not sufficiently confirmed by persons involved (such as Clinical Monitor, Data Manager and Statistician). > Confirmation destination becomes unclear when a problem occurs.	**Importance of Stakeholder Identification** When a question about a deliverable arises, it takes time to reply and may affect the planned schedule, if the department (function) to reply is not clear.
	Clarification of required quality and delivery date	**Agree on the content of work (deliverables)** in view of the collected data and the regulatory authority.	☐ Completed ☐ N/A		> Additional schedules and costs will be incurred, if the deliverable needed to be created is identified after the start of the operation. > Workload may increase, if Japanese characters are included in data (e.g. Translation into English and/or creating 2 datasets in both languages etc.). > Changes in operations may occur in case of multi-submission (FDA, PMDA, and others).	**Importance of Agreeing on the Deliverables** Unexpected actions may be required at the time of CDISC data generation because necessary data may not be collected or data entry outside of definition may be required, if all stakeholders have not a common understanding of collected data.
	Clarification of required quality and delivery date	Agree on the **condition for fixing** deliverables. - At time of interim Data Base Lock/Analysis - At time of final Data Base Lock/Analysis	☐ Completed ☐ N/A		> Quality standards become unclear. > Specification changes may endlessly occur, if the fixing conditions are not clearly defined.	
	Establishment of Process	Agree on the schedule, cost, communication route and deadline for additional work.	☐ Completed ☐ N/A		> Delayed notification of additional work may affect overall study schedule.	
	Establishment of Process	Clarify the **deadline for support** after delivery. - Until delivery of deliverables (Until completion of CDISC data) - Until regulatory submission - Until responding to inquiries from regulatory authorities	☐ Completed ☐ N/A		> Necessity and possibility of the response may be affected depending on the contents of the contract, if a submission error occurs at the time of electronic application via Gateway system or a client receives inquiries from the regulatory authorities after the application.	**Deadline of Supports** When the contractual coverage does not include actions to be taken in case of emergency at the NDA time, it may affect the planned NDA schedule since extended contract is required and this prevents a prompt action.
	Clarification of required quality and delivery date	Agree on the **timing for fixing** the deliverables (according to study milestones).	☐ Completed ☐ N/A		> Timing of fixing the deliverables becomes unclear. - CRO cannot secure enough work schedule for approval process. - CRO cannot predict when to bill.	**Fixation Timing of the Deliverables** The schedule required for approval cannot be secured, if the fixation timing of the deliverables has not been defined preliminarily. If the fixation timing is not clear, it becomes ambiguous from which point the specification change is a revision (additional work), which may lead a misunderstanding between sponsor and CRO.
	Establishment of Process	Clarify the **role of the person in charge** (prepare Who's who list etc.).	☐ Completed ☐ N/A		> In particular, in Data Management organization, there are cases where different persons are in charge of an existing DM contact and a SDTM specific contact, and it is sometimes difficult to find out who to contact. Be careful when the person in charge is changed.	
	Clarification of required quality and delivery date	Agree on the **timing and standpoint for reviewing** the deliverables with sharing study milestones. Notify immediately in case of any additions or changes.	☐ Completed ☐ N/A		> It may not be possible to respond without early notification, if milestones are expected to differ from those previously agreed (for example, submitting special data).	**Timing and Standpoint of the Review** Ensure a realistic schedule that both companies can handle. For the standpoint of the review, the necessity of the QC check is determined based on the quality which was set for the milestone as needed.
	Establishment of Process	Share information about external data. - Clarification of contractual coverage with a vendor - Contact person for vendor (depending on contractual coverage) - Number and timing of exchanges (including sample data) - Sharing data structure definition document - Handling of Blinded Data	☐ Completed ☐ N/A		> Study schedule may be delayed due to additional work. > Contacts are unclear when a problem occurs. > Schedule may be affected by additional work, if the data structure definition differs from the actual data structure. > There is a concern that confusion may occur just before the delivery time, if the person in charge and delivery method of the blinded data are not clear.	
	Clarification of required quality and delivery date	Agree on the **policy for handling Validation Rule** (handling instruction of "Error" and "Warning").	☐ Completed ☐ N/A		> Excessive resources are required for additional work which is not necessarily important to quality.	
	Clarification of required quality and delivery date	Agree on the delivery method. - m5 folder format - Other format	☐ Completed ☐ N/A		> It may squeeze the schedule due to revision of the procedures shortly before delivery time.	
In progress	Establishment of Process	Set and agree on **frequency and checking items for progress management** in advance.	☐ Completed ☐ N/A		> Schedule may be affected by discrepancies in information between outsourcer and outsourcee.	**Example of Check Items** - Are there any changes in the study milestone? - Isn't the planned schedule overreached? Unless information on the study schedule change (forward/backward) is shared between the two companies at any time, there is a possibility that the deliverables cannot be delivered at the required timing. Moreover, unnecessary actions for data generation and review may occur, which may lead to pressure on the resources of both companies.
At the end of work	Establishment of Process	Agree on **handling of the deliverables** after delivery is completed.	☐ Completed ☐ N/A		> Confusion may occur when the questions about details of the data arrive after a certain time.	
	Establishment of Process	**Review a series of operations** at a retrospective meeting.	☐ Completed ☐ N/A		> It will not lead to the improvement of the services from the next time, since the issues and the concerns have not been solved.	

Prerequisites for Contracted Business (Services)

(Revision of GSCPP Attachment 1)

Study Information	Study Title	
	Name of Study Drug (or Study Identification Code)	
	Study Phase	I / II / III / IV / PMS
	Therapeutic Area (or Indication)	
	Number of Subjects	
	Number of Study Sites	
	Materials can be provided at creating a quote	
Study Schedule	Study Conduction Period	YYYY/MM - YYYY/MM
	Patient Enrollment Period	YYYY/MM - YYYY/MM
	FPI (First Patient In) date	YYYY/MM
	LPO (Last Patient Out) date	YYYY/MM
	DBR (Database Release) date	YYYY/MM
	DBL (Database Lock) date	YYYY/MM
	SAC (Statistical Analysis Complete) date	YYYY/MM
	Observation Period	___ Week(s)
	Number of Visits	
Data Management	Type of CRF	EDC / Paper CRF
	Number of unique CRF pages (number of average items per CRF page:__)	
	Number of total CRF pages per subject	
	Number of Logical Checks	
	- Number of Logical Checks prepared in EDC system	
	- Number of External Logical Checks (using SAS programs etc.)	
	Number of Manual (Visual) Checks	
	Forms for CRF Review	Yes / No
	Forms for Progress Management	Yes / No
	External Data Import (Loading)	Yes / No
Statistical Analysis	Number of Forms (Table/List/Graph) - Unique Forms (T/L/G): - Repeated Forms (T/L/G):	
	Number of Statistical Analysis runs	
	- Final Analysis	Yes / No
	- Interim Analysis	Yes (__ times) / No
	- Immediate Analysis	Yes / No
	- Dry run	Yes (__ times) / No Please agree on the definition of the numbers (number of execution and/or output) in advance.
	- Blind Review	Yes / No
	DMC (Data Monitoring Committee)	
	-Statistical Analysis for DMC	Yes (__ times) / No
	-Secretariat of DMC	Yes / No
	Actions to PMDA's requirements such as inquiries	Yes / No
	Preparation of Case Investigation Meeting materials (Statistical Analysis related)	Yes / No
	PMDA Consultation	Yes / No
	Drafting Protocol (Statistical Analysis, Sample size, Study design)	Yes / No
	Consultation for Statistical Analysis related services other than those above	Yes / No
CDISC	Providing templates for various documents (CDISC related materials)	Yes / No
	Support communication with the client's global representative	Yes / No
	CDISC experience	Yes / No
	Attendance at the Pre-consultation meeting (if yes, please specify the number of attendances.)	Yes (__ times) / No
	Preparation of Attachment 8	Yes / No
	Preparation of Attachment 8-2	Yes / No
	Support to CDISC (support to standardization)	Yes / No
	Existence of client's standard	Yes / No
	(If Yes in the above) Existence of QC check items for the client's standard	Yes / No / N/A
	Support to Version Upgrade (thing to consider in case of long term study)	Yes / No
	Translation of Japanese language data	Yes / No
	Generate SDTM for Integration Analysis	Yes / No
	Generate ADaM for Integration Analysis	Yes / No
	Re-coding of data (for example, change of dictionary version at CDISC data conversion and/or conversion from Iyakuhin Data File to WHO-DD)	Yes / No

Overview of Services (DM/SDTM-EDC)

Please enter check mark or function name in the columns E to G.

(Revision of GSCPP Attachment 1)

Major Classification	Minor Classification	Items	Sponsor	CRO	EDC vendor	Remarks
Preparation	Protocol	Protocol review				
	eCRF	eCRF specification				
		eCRF completion guideline				
		Number of forms (___)				Please specify the number of Domains.
		Drafting (or reviewing) e-CRFs				
	Materials Preparation for Operation	Data Management Plan				
		Operating Procedures				
	Preparation for CRF Review	EDC logical check specification				
		External logical check specification				
		Manual (visual) check specification				
	EDC System Architecture	EDC system specification				
		EDC system design				
		Screen build				
		Edit check				
		CSV related matters				such as Unit test, Combined test
	Extra-EDC System Architecture (e.g. CDMS)	Extra-EDC system design				
		System architecture				
		CSV related matters				
	External Forms	Form design				
		Programming for the forms				
		CSV related matters				
	UAT	UAT Plan (including scripts)				
		UAT				
		UAT report				
	EDC System Training	Training				
		EDC operation manual (for study sites and client)				
Operation	Import External Data to External System	Import external data such as laboratory values to external system for checking				
	Transfer and Input Data to External System	Transfer and input institutional standard values to external system for checking				
	CRF Review	Check for automatically derived queries from EDC logical				
		External logical check				
		Manual (visual) check — Single				
		Manual (visual) check — Double				
	Query	Issuing queries on EDC				
		Check and confirmation of answers to queries				
		Query close				
	Coding	Adverse Events (MedDRA)				
		Past medical history & Concomitant disease (MedDRA)				
		Drug (WHO-DD, Iyakuhin Data File)				
	Delivery of External Forms	Delivery of external forms				
	SDTM Dataset	SDTM dataset generation (__ times) Breakdown (Dry run etc.):				Please specify the number of times and breakdown.
	Progress Management	Progress report				
	Account Issuance & Management	Account (ID, PASS) issuance & management				
	Help Desk					
Closing	DBL	Database Lock				
		Output and delivery subjects' data PDF				
	Case Investigation Meeting	Documentation of case handling criteria				
		Specification document for extraction of problematic cases				
		Programming				
		Output of extracted problematic cases				
		Input flag for data handling				
	Coding	Support for version upgrade of MedDRA				
	Dataset Generation	Documentation of procedures for SAS dataset generation				EDC data before SDTM conversion
		SAS dataset specification				same as above
		SAS dataset programming				same as above
		SAS dataset generation				same as above
	System Close	System decommission				
		Data archiving				
	Data Management Report	Data Management Report				
CDISC	CDASH	CDASH (Ver. __), CDASH-IG (Ver. __), Internal standard				Please specify the version number.
		CDASH Terminology (__ Edition)				Please specify the edition number.
	SDTM	SDTM generating Procedures				Please specify the development environment such as versions of SAS and Office.
		SDTM (Ver. __), SDTM-IG (Ver. __)				Please specify the version number.
		SDTM Terminology (__ Edition)				Please specify the edition number.
		Number of Standard Domains (___)				Please specify the number of Domains.
		Number of Custom Domains (__)				
		SDTM Annotated CRF				
		SDTM conversion specification				Mapping from Raw data to SDTM
		SDTM conversion programming Double programming Other ( )				Please specify the programming method.
		In case of "Other" in the above, please specify the following. Validation method of SDTM conversion program:				Please describe the contents and role allotment, if additional validation is required.
		SDTM data validation (__ times) Pinnacle 21 (PMDA / FDA / Both) Other ( )				Please specify the number of times and validator.
	Define	Define-XML (Ver. __)				Please specify the version number.
		Define-pdf				
	Study Data Reviewer's Guide	Study Data Reviewer's Guide (Ver. __) Language (Japanese / English)				Please specify the language and PhUSE template version number.
Others	Expenditure	Costs for system usage, maintenance and operation				
	Materials Storage	During operation period				
		Storage materials (in external warehouse etc.) from the end of operation to some period (until NDA submission)				
	Meeting Expenses	Meetings with client				
	Project Management Expenses	Overall business management Communication and sending documents				

X:Execute -:Not execute

Overview of Services (DM/SDTM-Paper CRF)

Please enter check mark or function name in the columns E & F.

(Revision of GSCPP Attachment 1)

Major Classification	Minor Classification	Items		Sponsor	CRO	Remarks
Preparation	Protocol	Protocol review				
	CRF	Creating (or reviewing) draft CRFs				
		Creating (or reviewing) CRF completion guideline				
		Number of Forms (___)				Please specify the number of Domains.
	Materials Preparation for Operation	Data Management Plan				
		Operating Procedures				
		Database structure definition				
		Annotated CRF				Annotations between CRF and Variables in Database
		Data entry manual				
		DCF (model form)				
	Preparation for CRF Review	Logical check specification				
		Manual (visual) check specification				
	DM System	Database design				
		Constructions of database and data entry screen				
		Programming for logical check				
		e-Data import				
		CSV related matters				
	External Forms	Form design				
		Programming for the forms				
		CSV related matters				
	CSV	Validation Plan (including scripts)				
		Validation				
		Validation Report				
Operation	Import External Data to External System	Import external data such as laboratory values to external system for checking				
	Transfer and Input the Institutional Standard Values to External System	Transfer and input institutional standard values to external system for checking				
	CRF Receiving (copy or original)	Receiving CRFs (copy or original)				
	CRF Image	Creating PDF file of CRFs				
	Data Entry	Data entry	Single entry			
			Double entry			
		Quality evaluation of database (final confirmation)	Reading verification of all data or 3rd data entry			
			Reading verification of random sampling data (10,000 fields)			Acceptable error rate Critical Data：0～0.1% Non-critical Data：0.2～1%
	CRF Review	Logical check				
		Manual (visual) check	Single			
			Double			
	Query	DCF				
		Check and confirmation of answers to queries				
	Coding	Adverse Events (MedDRA)				
		Past medical history & Concomitant disease (MedDRA)				
		Drug (WHO-DD, Iyakuhin Data File)				
	Delivery of External Forms	Delivery of external forms				
	SDTM Dataset	SDTM dataset generation (__ times) Breakdown (Dry run etc.):				Please specify the number of times and breakdown.
	Progress Management	Progress report				
Closing	DBL	Temporal Database Lock				
		Final Database Lock				
	Case Investigation Meeting	Documentation of case handling criteria				
		Specification document for extraction of problematic cases				
		Programming				
		Output of extracted problematic cases				
		Input flag for data handling				
	Coding	Support for version upgrade of MedDRA				
	Dataset Generation	Documentation of procedures for SAS dataset generation				CRF data before SDTM conversion
		SAS dataset specification				same as above
		SAS dataset programming				same as above
		SAS dataset generation				same as above
	Data Management Report	Data Management Report				
CDISC	CDASH	CDASH (Ver. __), CDASH-IG (Ver. __), Internal standard				Please specify the version number.
		CDASH Terminology (___ Edition)				Please specify the edition number.
	SDTM	SDTM generating Procedures				Please specify the development environment such as versions of SAS and Office.
		SDTM (Ver. __), SDTM-IG (Ver. __)				Please specify the version number.
		SDTM Terminology (___ Edition)				Please specify the edition number.
		Number of Standardized Domains (__)				Please specify the number of Domains.
		Number of Customized Domains (__)				
		SDTM Annotated CRF				
		SDTM conversion specification				Mapping from Raw data to SDTM
		SDTM conversion programming				Please specify the programming method.
		In case of "Other" in the above, please specify the following. Validation method of SDTM conversion program:				Please describe the contents and role allotment, if additional validation is required.
		SDTM data validation (__ times) Pinnacle 21 (PMDA / FDA / Both)				Please specify the number of times and validator.
	Define	Define-XML (Ver. __)				Please specify the version number.
		Define-pdf				
	Study Data Reviewer's Guide	Study Data Reviewer's Guide (Ver. __) Language (Japanese / English)				Please specify the language and PhUSE template version number.
Others	Expenditure	Costs for system usage, maintenance and operation				
	Materials Storage	During operation period				
		Storage materials (in external warehouse etc.) from the end of				
	Meeting Expenses	Meetings with client				
	Project Management Expenses	Overall business management				

X:Execute -:Not execute

Overview of Services (Statistical Analysis)

Please enter check mark or function name in the columns F & G.

(Revision of GSCPP Attachment 1)

Major Classification	Minor Classification	Items			Sponsor	CRO	Remarks
Preparation	Operating Procedures for Statistical Analysis	Operating procedure for Statistical Analysis					Please specify the development environment such as versions of SAS and Office.
	Statistical Analysis Plan	Statistical Analysis Plan Version update (planned number of revisions: __ times)					
	Mockup	Mockup (Table/List/Graph for analysis) Version update (planned number of revisions: __ times)					
	Analysis Program Validation Plan	Analysis program validation plan					
	Analysis Dataset	Analysis dataset specification					This is a case when submitting data in a format other than ADaM (Phase I study, Clinical pharmacology study etc.).
		Analysis dataset programming (including program verification work)	Programming	Single			
				Double			
	Programming for Analysis	Analysis program specification					
		Programming for analysis (including program verification work)	Programming	Single			Consider submitting the programs.
				Double			
	Analysis Program Validation	Validation Plan for analysis / Validation Report for analysis					
CDISC	ADaM	ADaM (Ver. __), ADaM-IG (Ver. __)					Please specify the version number.
		ADaM Terminology (__ Edition)					Please specify the edition number.
		Number of Datasets (__)					Please specify the number of datasets.
		ADaM data validation (__ times) Pinnacle 21 (PMDA / FDA / Both) Other ( )					Please specify the number of times and validator.
		ADaM data specification					
		ADaM data generating program	Programming	Single			Consider submitting the programs.
				Double			
	Analysis Results Metadata	Analysis Results Metadata Create the metadata including Define (Yes / No)					
	Define	Define-XML (Ver. __)					Please specify the version number.
		Define-pdf					
	Analysis Data Reviewer's Guide	Analysis Data Reviewer's Guide (Ver. __) Language (Japanese / English)					Please specify the language and PhUSE template version number.
Operation	Analysis Execution	Number of ADaM/Analysis dataset creations (__ times) Breakdown (Dry run etc.):	Programming	Single			Please specify the number of times and breakdown.
		ADaM/Analysis dataset Re-run					
		Execution of analysis	Programming	Single			
		Re-execution of the programs					
Closing	Statistical Analysis Report	Statistical analysis report					
	Statistical Analysis Work Report	Statistical analysis work report					
Others	Expenditure	Costs for system usage, maintenance and operation					
	Materials Storage	During operation period					
		Storage materials (in external warehouse etc.) from the end of operation to some period (until NDA submission)					
	Meeting Expenses	Meetings with client					
	Project Management Expenses	Overall business management Communication and sending documents					
Option Please enter any special instructions that are not described in the prerequisites.	DMC	-Statistical Analysis for DMC					
		-Secretariat of DMC					
	Actions to PMDA's Requirements such as inquiries						
	(Statistical Analysis related) Documentation for Case Investigation Meeting						
	Final Analysis	-Deliverables: -QC: Necessary ( ) / Unnecessary					Please confirm the SDTM in the same way.
	Interim Analysis	-Deliverables: -QC: Necessary ( ) / Unnecessary					Please confirm the SDTM in the same way.
	Immediate Analysis						
	Dry Run	-Purpose: Layout check / Results check / Other -Scope: Efficacy: __ forms / Safety: __ forms -QC: Necessary ( ) / Unnecessary					
	Blind Review						
	PMDA Consultation						
	Preparation of Attachment 8						
	Preparation of Attachment 8-2						
	Drafting Protocol (Statistical Analysis, Sample size, Study design)						
	Consultation for Statistical Analysis Related Services other than those above						

X:Execute -:Not execute