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TECHNICAL GUIDANCE ON THE FORMAT OF THE DATA FIELDS OF RESULT-RELATED INFORMATION ON CLINICAL TRIALS SUBMITTED IN ACCORDANCE WITH ARTICLE 57(2) OF REGULATION (EC) NO 726/2004 AND ARTICLE 41(2) OF REGULATION (EC) NO 1901/2006

Document history:	
Date of closure of public consultation	30 September 2010
Date of meeting of "Ad-hoc group for the development of implementing guidelines for the 'Clinical Trials Directive' 2001/20/EC":	18 December 2012
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Introduction

In its *Guidance 2012/C302/03 on posting and publication of result-related information on clinical trials in relation to the implementation of Article 57(2) of Regulation (EC) No 726/2004 and Article 41(2) of Regulation (EC) No 1901/2006*[1] the Commission has announced, under point 3., publication of implementing technical guidance on the format of the data fields in relation to result-related information.

This document contains this implementing technical guidance. It provides a visual representation of the clinical trial results data that is required to be captured by EudraCT. It also provides details of how the fields are organised.

Results may be displayed EU Clinical Trials register in a different visual representation.

This document does not describe the user interface design for entry of results data in EudraCT.

For additional regulatory information, reference is made to the Commission Guidance 2012/C302/03.

Technical information on EudraCT is available at https://eudract.ema.europa.eu/index.html.

[1] OJ C302, 6.10.2012, p. 7.

Clinical Trial Results - contents:

Trial information:
- Study identification
- Identifiers
- Sponsor details
- Paediatric regulatory details
- Result analysis stage
- General Information about the trial
- Population of trial subjects with actual number of subjects included in the trial

Subject disposition:
- Recruitment
- Pre-assignment Period
- Post Assignment Periods

Baseline Characteristics:
- Baseline Characteristics (Required) Age
- Baseline Characteristics (Required) Gender
- Baseline Characteristics (Optional) Study Specific Characteristic

End Points:
- Endpoint definitions
- End Point #1
  - Statistical Analyses
- End Point #2,
  - Statistical Analyses
- etc

Adverse Events:
- Adverse events information
- Adverse event reporting group
- Serious Adverse Events
- Non-serious adverse event

More Information:
- Global Substantial Amendments
- Global Interruptions and re-starts
- Limitations & Caveats

Title of trial

Full Title of the trial	

Trial Identifiers

EudraCT Number ①			**Sponsor Protocol Code**			
Other Trial Identifiers						
Other Identifier name	ISRCTN Number	NCT Number	WHO Universal Trial Reference Number (UTRN)			
Other Identifier						

Sponsor

Organisation Name			
Street Address		**Town/City**	
Post code		**Country**	

Contact Points - **Scientific Contact Point**

Functional name of contact point		**Name of organisation**	
Telephone number			
Email address			

Contact Points - **Public contact point ②**

Functional name of contact point		**Name of organisation**	
Telephone number			
Email address			

Paediatric regulatory details

Is trial part of a Paediatric Investigation Plan?	***[Circle one]*** Yes/No				
EMA Paediatric Investigation Plans					
Does article 45 REGULATION (EC) No 1901/2006 apply to this trial?	***[Circle one]*** Yes/No		**Does article 46 REGULATION (EC) No 1901/2006 apply to this trial?**	***[Circle one]*** Yes/No	

Result analysis stage

Primary completion date reached?	***[Circle one]*** Yes/No	**Primary completion date**	
Analysis stage	***[Circle one]*** Interim; Final	**Date of interim/final analysis**	
Global end of trial reached?	***[Circle one]*** Yes/No	**Date of global end of trial**	

General information about trial

Main objective of the trial			
Actual date of start of recruitment to the protocol (in any country)			
Long term follow up planned	***[Circle one]*** Yes/No	**Follow up planning rationale**	
Long term follow up duration	Value: _____ Unit: *[Select one]* Months; Years		

Independent Data-Monitoring Committee (IDMC) involvement	***[Circle one]*** Yes/No
Protection of subjects ③	

Background therapy ④	
Evidence for comparator(s)	

Actual number of subjects included in the trial

Actual number of subjects included in each Country concerned

Country										
Number of subjects										

For multinational trials

Actual number of subjects included in the EEA	[Derived from table above]
Actual number of subjects included worldwide	[Derived from table above]

Age Group Breakdown for the whole trial

Age of subjects	**Number of Subjects**
In Utero	
Preterm newborn- gestational age < 37 wk	
Newborns (0-27days)	
Infants and toddlers (28days – 23months)	
Children (2-11 years)	
Adolescents (12-17 year)	
Between 18 and 65 years	
From 65 years to 84 years	

85 years and over	

① The EudraCT number cannot be amended

② The public contact and scientific contact points may be the same as each other.

③ A description of the actual measures taken to protect subjects.

④ Details such as the dosage and frequency plus any other relevant information should be captured here.

Subject disposition form *EMA*

Recruitment Details ①	
Screening Details ②	

Pre-Assignment Period **Title: Pre-Assignment Period**

		Number of Subjects
STARTED		
Milestone Title ③		
Milestone Title ③		
COMPLETED		
Reason Not Completed		[Derived: started – completed]
Adverse event, not serious		
Adverse event, serious fatal		
Adverse event, serious non-fatal		
Consent withdrawn by subject		

Physician decision		
Pregnancy		
Protocol Violation		
Other Reason ④		
Other Reason ④		

① Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and types of location (e.g. medical clinic), to provide context.

② Screening details are required if the results will not contain a pre-assignment period.

③ Add as many Milestone Title. A descriptive title for each row is required.

④ Add as many other reason not completed rows as needed. A descriptive title for each row is required.

Period ① **Title: Title Name:**_____ **Baseline Period: Yes/No** [Circle one]

Blinding	***[Circle one]*** Double blind; Single blind ; Not applicable	**Roles blinded ②**	***[Circle any]*** Subject; Investigator; Monitor; Data analyst; Carer ; Assessor
Blinding implementation details			
Allocation Method	***[Circle one]*** Randomised – controlled; Non-randomised – controlled; Not applicable		

Arm Title ③				**TOTAL**
Arm Description ④				
	Number of Subjects	**Number of Subjects**	**Number of Subjects**	**Number of Subjects**
STARTED				[Derived: total STARTED]
Milestone Title ⑤				[Derived: total Milestone]
Milestone Title ⑤				[Derived: total Milestone]
COMPLETED				[Derived: total COMPLETED]
Reason Not Completed ⑥				
Adverse event, not serious				[Derived: total for reason]
Adverse event, serious fatal				[Derived: total for reason]
Adverse event, serious non-fatal				[Derived: total for reason]

Consent withdrawn by subject				[Derived: total for reason]
Lack of Efficacy				[Derived: total for reason]
Lost to follow-up				
Physician decision				[Derived: total for reason]
Pregnancy				[Derived: total for reason]
Protocol Violation				[Derived: total for reason]
Transferred to other arm/group				[Derived: total for reason]
Other Reason ⑦				[Derived: total for reason]
Other Reason ⑦				[Derived: total for reason]
Reasons for joining				
Transferred in from other arm/group				[Derived: total for reason]
Late recruitment				[Derived: total for reason]
Other reason ⑧				[Derived: total for reason]
Other reason ⑧				[Derived: total for reason]

① Complete a period table for each period you wish to report. Provide a descriptive title for each reported period.

② If blinding is single or double, then the roles blinded must be specified.

③ Arms are created on the next form. Only the Arm title and description will be displayed on the Subject disposition form

④ Arm Description provides more details about the Arm.

⑤ Add as many Milestone Titles as necessary. A descriptive title for each row is required.

⑥ Use only the most appropriate reason for not completing in each case and do not double count.

⑦ Add as many other reason not completed rows as needed. A descriptive title for each row is required.

⑧ Add as many other reasons for joining the Arm as needed. A descriptive title for each row is required.

Subject disposition arm form □ *EMA*

Arm Title	
Arm Description ②	
Arm Type	***[Circle one]*** Experimental; Active Comparator; Placebo Comparator; No IMP; Other (specify):_____

Products used ③

IMP Name	
IMP Code	
Other names (separated by commas)	
Route of Administration ④	*Select any number of terms from the human domain of the EUTCT List*
Pharmaceutical Form ⑤	*Select any number of terms from the human domain of the EUTCT List*
Dosage and Administration Details ⑥	

① This form is used to create the Arms used as reference information in the Subject disposition details (see previous)

② Arm Description describes details about the arms evaluated.

③ Details of the products used. There may be multiple products created.

④ A product may have any number of Routes of Administration

⑤ A product may have any number of Pharmaceutical Forms

⑥ Provide any or all of the following details: the dosage and frequency of administration.

Subject analysis sets form *EMA*

Subject analysis set ①

Subject analysis set title	
Subject analysis set type	***[Circle one]*** Intent to treat; Per protocol; Full analysis set; Safety population; Sub-group analysis set
Subject analysis set description②	
Number of subjects③	

① Complete a subject analysis set table for additional groups of subjects you wish to report on.

② Subject analysis set description that defines the population type.

③ Provide the number of subjects that constitute this subject analysis set.

Baseline characteristics form Age *EMA*

Reporting Group Title				TOTAL
Reporting Group Description ①				
Overall number of baseline subjects				[Derived: total]
Age, Categorical ②	Number of subjects	Number of subjects	Number of subjects	Number of subjects
Unit of measure: Subjects				
In Utero				[Derived: category total]
Preterm newborn- gestational age < 37 wk				[Derived: category total]
Newborns (0-27days)				[Derived: category total]
Infants and toddlers (28days – 23months)				[Derived: category total]
Children (2-11 years)				[Derived: category total]
Adolescents (12-17 year)				[Derived: category total]
From 18 - 64 years				[Derived: category total]
From 65 – 84 years				[Derived: category total]
Over 85 years				[Derived: category total]

Age, Continuous		**Measure type**	**Dispersion type**	**Measure type**	**Dispersion type**	**Measure type**	**Dispersion type**		
		[Circle One] arithmetic mean, geometric mean, least squares mean, log mean, median.	***[Circle One]*** standard deviation, interquartile range, range, sample min/max.	***[Circle One]*** arithmetic mean, geometric mean, least squares mean, log mean, median.	***[Circle One]*** standard deviation, interquartile range, range, sample min/max.	***[Circle One]*** arithmetic mean, geometric mean, least squares mean, log mean, median.	***[Circle One]*** standard deviation, interquartile range, range, sample min/max.		
Unit of measure									

① Reporting group description contains details about the group of subjects receiving treatment.

②The age categories above are the default categories that match the protocol details in the clinical trial application. However, any age categorisation can be used.

Baseline characteristics form Gender *EMA*

Reporting group title				**TOTAL**
Reporting group description ①				
Overall number of baseline subjects				**[Derived: total]**
Gender, female, male ②	**Number of subjects**	**Number of subjects**	**Number of subjects**	**Number of subjects**
Unit of measure Subjects				
Female				**[Derived: category total]**
Male				**[Derived: category total]**

① Reporting group description contains details about the group of subjects receiving treatment.

② At least one Gender baseline measure (female, male or Customised) is required

Study specific characteristic title	
Baseline measure description	

Reporting group title								**TOTAL ④**	
Reporting group description ①									
Overall number of baseline subjects								**[Derived: total]**	
Unit of Measure		**Measure type**	**Dispersion type**	**Measure type**	**Dispersion type**	**Measure type**	**Dispersion type**	**Measure type**	**Dispersion type**
		[Circle One] arithmetic mean, geometric mean, least squares mean, log mean, median.	***[Circle One]*** ② standard deviation, interquartile range, range, sample min/max.	***[Circle One]*** arithmetic mean, geometric mean, least squares mean, log mean, median,	***[Circle One]*** ② standard deviation, interquartile range, range, sample min/max.	***[Circle One]*** arithmetic mean, geometric mean, least squares mean, log mean, median.	***[Circle One]*** ② standard deviation, interquartile range, range, sample min/max.		
		Number of subjects		**Number of subjects**		**Number of subjects**		**Number of subjects**	

Category Title ③					**[Derived: category total]**
Category Title ③					**[Derived: category total]**
Category Title ③					**[Derived: category total]**

① Reporting group description contains details about the group of subjects receiving treatment.

② A single number should be entered for all dispersion types in this table.

③ Add as many Categories as needed if the data can be categorised.

④ The total group is only relevant to categorical data.

End Point Type	***[Circle one]*** ***Primary*** ***Secondary*** ***Other Pre-specified*** ***Post-Hoc***
End Point Title	
End Point Description **[Max. 999 characters]**	
End Point Time Frame **[Max. 255 characters]**	
Arm(s)/Subjects analysis sets	Select from the Arms within a Period or Subject analysis sets specified above

Reporting Group Title								
Reporting Group Description ①								
Overall Number of Baseline Subjects		**Comment②**			**Comment②**			**Comment②**	
	Measure type	**Dispersion / Precision type**		**Measure type**	**Dispersion / Precision type**		**Measure type**	**Dispersion / Precision type**

		[Circle One] number, arithmetic mean, least squares mean, geometric mean, log mean, median.	*[Circle One]* ③ not applicable, standard deviation, inter-quartile range, range, sample min/max, standard error, confidence interval (percentage).	*[Circle One]* number, arithmetic mean, least squares mean, geometric mean, log mean, median.	*[Circle One]* ③ not applicable, standard deviation, inter-quartile range, range, sample min/max, standard error, confidence interval (percentage).	*[Circle One]* number, arithmetic mean, least squares mean, geometric mean, log mean, median.	*[Circle One]* ③ not applicable, standard deviation, inter-quartile range, range, sample min/max, standard error, confidence interval (percentage).
Unit of Measure							
Category Title ⑤			④		④		④
Category Title ⑤			④		④		④

Graphical Representation

Upload images containing the graphical representation relevant to the End point.

① Reporting group description contains details about the group of subjects receiving treatment.

② A comment explaining why the number of subjects for the variable differs to the number of subjects in the selected arm.

③ “Not applicable” Dispersion/Precision type should not be used only when Measure type is not “number”.

④ Numeric lower and upper values should be entered when precision type is a “confidence interval”. A single number should be entered for all other Dispersion/Precision types.

⑤ Add as many categories as needed if the end point can be categorised.

Below is the definition of the statistical analysis details for this variable

Statistical Analysis of End Point ①

Statistical analysis title		**Analysis Type**	***[Circle one]*** Non-Inferiority; Equivalence; Superiority; Other
		Comment	
Statistical analysis description			
Comparison group	**Omnibus analysis:** ***[Circle one]*** All reporting groups, All subject analysis sets		**Selection of Reporting groups:_____** ②
Number of subjects	**[Value is derived: sum of subjects from groups/subject analysis sets]**		
Analysis specification	***[Circle one]*** Pre-specified; Post hoc		
Statistical hypothesis test			
P-value	***[Circle one]*** = < ≤ > ≥ ③	Value:_____	**Comment ④**
Method **[Required if P-value provided]**	***[Circle one]*** ANCOVA; ANOVA; Chi-squared; Chi squared Corrected; Cochran-Mantel-Haenszel; Fisher Exact; Kruskal-Wallis; Logrank; Mantel-Haenszel ; McNemar; Mixed Models Analysis; Regression, Cox; Regression, Linear; Regression, Logistic; Sign Test; t-Test 1-sided; t-Test 2-sided; Wilcoxon (Mann-Whitney); Other method name: (specify)_____		
Parameter Estimate			

Point estimate								
Confidence interval	**Level**	**95%; 90%; Other:_____%**	**Sides**	***[Circle one]*** **1 2**	**Lower limit**		**Upper limit**	
Parameter type	***[Circle one]*** Cox Proportional Hazard; Hazard Ratio(HR); Hazard Ratio Log, Mean Difference (Final Values); Mean Difference (Net); Median Difference (Final Values); Median Difference (Net); Odds Ratio (OR); Odds Ratio log; Risk Difference (RD); Risk Ratio (RR); Risk Ratio log; Slope Other effect estimate: (specify)_____							
Variability estimate	***[Circle one]*** Standard Deviation; Standard Error of the Mean			**Dispersion Value**				

① Add any number of statistical analyses for each end point as required.

② Select the reporting groups from those included in the end point that are relevant to this statistical analysis if an omnibus analysis is not being performed.

③ Prefix the P-value with a comparison operator.

④ This field contains additional information about the P-value such as whether it is adjusted for multiple comparisons and a priori threshold for statistical significance.

Time Frame for Adverse Event Reporting [max 255 characters]				
Adverse Event Reporting Additional Description [max 350 characters]				
Dictionary Used ①	**Dictionary Name**	***[Circle One]*** MedDRA; SNOMED CT; Other:(specify)_____	**Dictionary Version**	
Method	***[Circle one]*** Systematic; Non-Systematic		**Frequency threshold for reporting non-serious adverse events ②**	_____%

Serious adverse events

Reporting Group Title			
Reporting Group Description ③			
Number of subjects exposed			
Number of subjects affected by serious adverse events			

Number of subject affected by non-adverse events			
Number of deaths (all causes)			
Number of deaths resulting from adverse events			

Serious Adverse Events

System Organ Class	**Event Term**	**Additional Description**	**Dictionary**	*Number of Subjects* ***affected***	*Number of Subjects* ***exposed***	***Event term Occurrences - all***	*Event Term Occurrences - causally related to the treatment*	*Number of Subjects* ***Affected***	*Number of Subjects* ***exposed***	*Event term Occurrences - all*	*Event term Occurrences- causally related to the treatment*	*Number of Subjects* ***Affected***	*Number of Subjects* ***exposed***	*Event term occurrences - all*	*Event term Occurrences- causally related to the treatment*
					④				④				④		
					④				④				④		
					④				④				④		
					④				④				④		

FATALITIES

System Organ Class	**Event Term**		*Fatalities - all*	*Fatalities - causally related to the treatment*	*Fatalities - all*	*Fatalities - causally related to the treatment*	*Fatalities - all*	*Fatalities - causally related to the treatment*

	⑤							
	⑤							
	⑤							
	⑤							

Non-serious adverse events

Reporting group title			
Reporting group description			
Number of subjects affected by non-serious adverse events			

Non-serious Adverse Events															
				*Number of Subjects **affected***	*Number of Subjects **exposed***	***Event term Occurrences - all***	*Event Term Occurrences - causally related to the treatment*	*Number of Subjects **Affected***	*Number of Subjects **exposed***	*Event term Occurrences - all*	*Event term Occurrences- causally related to the treatment*	*Number of Subjects **Affected***	*Number of Subjects **exposed***	*Event term occurrences - all*	*Event term Occurrences- causally related to the treatment*
System Organ Class	**Event Term**	**Additional Description**	**Dictionary**												
					④				④				④		
					④				④				④		
					④				④				④		
					④				④				④		

① The table defaults provide a short-cut for entering the dictionary used for recording all Adverse events in a study. If entered, the table default values respectively apply to any Adverse Event with a blank Dictionary name.

② The frequency of non-serious adverse events that, when exceeded within any arm or comparison group, are reported in the results database for all arms or comparison groups. The number must be less than or equal to the allowed maximum expressed as a percentage. For example, a threshold of 5 per cent indicates that all non-serious adverse events with a frequency greater than 5 per cent within at least one arm or comparison group are reported.

③ Reporting group description contains details about subjects in this group.

④ Number of subjects exposed for a single Adverse event in a reporting group is only required when the value differs from the Total number of subjects at exposed in the reporting group.

⑤ The event terms used for reporting fatalities must also appear in the serious adverse events table.

More Information *EMA*

*Global Substantial Protocol Amendments*①

Amendment Date	Description

*Global Interruptions and Restarts*②

Interruption Date	Description	Restart Date

*Limitations and Caveats*③

Limitations and Caveats that apply to the results

① Provide details of the substantial amendments to the protocol that affected the trial globally. There may not have been any global substantial protocol amendments, so their presence is optional. However if a global substantial protocol amendment is created, then both the date and the description are necessary. There is sufficient provision to support the presence of any number of global substantial protocol amendments to the trial.

② Provide details of the interruptions that affected the trial globally. There may not have been any global interruptions, so their presence is optional. If a global amendment is created it must have an interruption date and a description. The restart date is provided only if the trial was restarted globally after the interruption. There is sufficient provision to support the presence of any number of global interruptions and restarts to the trial.

③ Based on the conduct of the trial provide any limitations or caveats to the results of the trial.