Trial Design Datasets

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26th Meeting
German CDISC User Network

20.02.2018 / Michael Schmitz /

Agenda

- **Hintergrund**
- **CDISC Study Design Workbook**
  - TS – Trial Summary
  - TE – Trial Elements
  - TA – Trial Arms
  - TV – Trial Visits
  - TI – Trial Inclusion/Exclusion Criteria
- **Herausforderungen**

Hintergrund

Hintergrund

Im Rahmen der Einführung des Adjustable Study Planning (ASP) wurden verschiedene Protokoll Level festgelegt, die einen definierten Zustand beschreiben.

Protocol Data Elements	Protocol Level 0	Protocol Level 1	Protocol Level 2
Primary / Secondary enpoints			
Key Inclusion / Exclusion criteria			
Study Design			
Potential countries			
Visit schedule			
Number of patients			
Number of sites			
Treatment			
Comparators			

stable
final

CDISC Study Design Workbook

TS – Trial Summary

Protocol level 1

TSSEQ	TSGRPID	TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER	Expectation	Guidance
1		ACTSUB	Actual Number of Subjects		NAV		ISO 21090		REQ	TSVAL is
1		AGEMAX	Planned Maximum Age of Subjects		PINF		ISO 21090		REQ	CDISC: If there
1		AGEMIN	Planned Minimum Age of Subjects	P18Y			ISO 8601		REQ	CDISC: If there
1	2	COMPTRT	Comparative Treatment Name	COMPARATOR A		E47C0NF7LV	UNII		PERM	
1	1	DOSE	Dose per Administration	0,3					PERM	
2	1	DOSE	Dose per Administration	0,6						
1	1	DOSFRQ	Dosing Frequency	ONCE		C64576	CDISC	2017-03-31	PERM	
2	2	DOSFRQ	Dosing Frequency	QD		C25473	CDISC	2017-03-31	PERM	
1	1	DOSU	Dose Units	mg/kg		C67401	CDISC	2017-03-31	PERM	
2	2	DOSU	Dose Units	mg		C28253	CDISC	2017-03-31	PERM	
1		FCNTRY	Planned Country of Investigational Sites	AUS		ISO 3166			REQ	CDISC: Use as
1		INGRDNT	Active Ingredient in Test Product	BAY abc					PERM	Sponsor specific
1		SPONSOR	Clinical Study Sponsor	BAYER HEALTHCARE LLC		112117283	DUNS	2017-05-04		
1		OBJPRIM	Trial Primary Objective	To assess the safety and efficacy of different doses of ...					REQ	CDISC Assumpt.
1		OUTMSPRI	Primary Outcome Measure	The incidence of composite endpoint consisting of ...					REQ	CDISC Assumpt.
1		OBJSEC	Trial Secondary Objective	To compare the safety and efficacy of BAY abc with ...					PERM	CDISC Assumpt.
1		OUTMSSEC	Secondary Outcome Measure	The incidence of symptomatic DVT or non-fatal PE, ...					PERM	CDISC Assumpt.
1		LENGTH	Trial Length	P160D			ISO 8601		REQ	Sponsor:
1		NARMS	Planned Number of Arms	12					REQ	CDISC: TSVAL is
1		PLANSUB	Planned Number of Subjects	700					REQ	CDISC: TSVAL is
1		RANDOM	Trial is Randomized	Y		C49488	CDISC	2017-03-31	REQ	Sponsor: Origin:
1		RANDQT	Randomization Quotient	0.714					CondREQ	CDISC: TSVAL is
1		REGID	Registry Identifier	2016-002681-31		2016-002681-31	EUDRAC		REQ	CDISC: Use as
1	1	ROUTE	Route of Administration	INTRAVENOUS DRIP		C38279	CDISC	2017-03-31	REQ	
2	2	ROUTE	Route of Administration	SUBCUTANEOUS		C38299	CDISC	2017-03-31		
1		STYPE	Study Type	INTERVENTIONAL		C98388	CDISC	2017-03-31	REQ	
1		TIMEW	Time Window in Days (TESS)		NAV		ISO 21090		REQ	Sponsor specific
1		TPHASE	Trial Phase Classification	PHASE IIA TRIAL		C49686	CDISC	2017-03-31	REQ	Sponsor: Origin:
1		TTYPE	Trial Type	SAFETY		C49667	CDISC	2017-03-31	REQ	CDISC: Use as
2		TTYPE	Trial Type	EFFICACY		C49666	CDISC	2017-03-31	REQ	

Required column	stable
Expected column	final
Permissible column	
Description column	
Bayer specific parameter	

TS – Trial Summary

Protocol level 2

TSSEQ	TSGRPID	TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER	Expectation	Guidance
1		ACTSUB	Actual Number of Subjects		NAV		ISO 21090		REQ	TSVAL is
1		AGEMAX	Planned Maximum Age of Subjects		PINF		ISO 21090		REQ	CDISC: If there
1		AGEMIN	Planned Minimum Age of Subjects	P18Y			ISO 8601		REQ	CDISC: If there
1	2	COMPTRT	Comparative Treatment Name	COMPARATOR A		E47C0NF7LV	UNII		PERM	
1	1	DOSE	Dose per Administration	0,3					PERM	
2	1	DOSE	Dose per Administration	0,6						
1	1	DOSFRQ	Dosing Frequency	ONCE		C64576	CDISC	2017-03-31	PERM	
2	2	DOSFRQ	Dosing Frequency	QD		C25473	CDISC	2017-03-31	PERM	
1	1	DOSU	Dose Units	mg/kg		C67401	CDISC	2017-03-31	PERM	
2	2	DOSU	Dose Units	mg		C28253	CDISC	2017-03-31	PERM	
1		FCNTRY	Planned Country of Investigational Sites	AUS		ISO 3166			REQ	CDISC: Use as
1		INGRDNT	Active Ingredient in Test Product	BAY abc					PERM	Sponsor specific
1		SPONSOR	Clinical Study Sponsor	BAYER HEALTHCARE LLC		112117283	DUNS	2017-05-04		
1		OBJPRIM	Trial Primary Objective	To assess the safety and efficacy of different doses of ...					REQ	CDISC Assumpt.
1		OUTMSPRI	Primary Outcome Measure	The incidence of composite endpoint consisting of ...					REQ	CDISC Assumpt.
1		OBJSEC	Trial Secondary Objective	To compare the safety and efficacy of BAY abc with ...					PERM	CDISC Assumpt.
1		OUTMSSEC	Secondary Outcome Measure	The incidence of symptomatic DVT or non-fatal PE, ...					PERM	CDISC Assumpt.
1		LENGTH	Trial Length	P160D			ISO 8601		REQ	Sponsor:
1		NARMS	Planned Number of Arms	12					REQ	CDISC: TSVAL is
1		PLANSUB	Planned Number of Subjects	700					REQ	CDISC: TSVAL is
1		RANDOM	Trial is Randomized	Y		C49488	CDISC	2017-03-31	REQ	Sponsor: Origin:
1		RANDQT	Randomization Quotient	0.714					CondREQ	CDISC: TSVAL is
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1		TTYPE	Trial Type	SAFETY		C49667	CDISC	2017-03-31	REQ	CDISC: Use as
2		TTYPE	Trial Type	EFFICACY		C49666	CDISC	2017-03-31	REQ	

Required column
Expected column
Permissible column
Description column
Bayer specific parameter

stable
final

TE – Trial Elements

ETCD	ELEMENT	TESTRL	TEENRL	TEDUR
SCRN	SCREENING	Informed consent	Day before Randomization	
PRETRT	PRE-TREATMENT	Randomization	Date of first treatment	
SD0_3MG	BAY abc - 0.3 mg/kg	Date of first treatment	Date of last treatment	
SD0_6MG	BAY abc - 0.6 mg/kg	Date of first treatment	Date of last treatment	
COMEN	COMPARATOR	Date of first treatment	Date of last treatment	
POSTDOSE	POST DOSE	Day after last treatment	Date of bilateral venography	
POSTFUP	POST TREATMENT / FOLLOW-UP	Date after bilateral venography	Date of last visit	

Required column
Expected column

TA – Trial Arms

ARMCD	ARM	TAETORD	ETCD	ELEMENT	TABRANCH	TATRANS	EPOCH
abc0.3	abc-0.3 mg/kg	1	SCRN	SCREENING	Randomized to abc-0.3 mg/kg		SCREENING
abc0.3	abc-0.3 mg/kg	2	PRETRT	PRE-TREATMENT			TREATMENT
abc0.3	abc-0.3 mg/kg	3	SD0_3MG	BAY abc - 0.3 mg/kg			TREATMENT
abc0.3	abc-0.3 mg/kg	4	POSTDOSE	POST DOSE			TREATMENT
abc0.3	abc-0.3 mg/kg	5	POSTFUP	POST TREATMENT / FOLLOW-UP			POST TREATMENT OBSERVATION PERIOD
abc0.6	abc-0.6 mg/kg	1	SCRN	SCREENING	Randomized to abc-0.6 mg/kg		SCREENING
abc0.6	abc-0.6 mg/kg	2	PRETRT	PRE-TREATMENT			TREATMENT
abc0.6	abc-0.6 mg/kg	3	SD0_6MG	BAY abc - 0.6 mg/kg			TREATMENT
abc0.6	abc-0.6 mg/kg	4	POSTDOSE	POST DOSE			TREATMENT
abc0.6	abc-0.6 mg/kg	5	POSTFUP	POST TREATMENT / FOLLOW-UP			POST TREATMENT OBSERVATION PERIOD
COMPA	COMPARATOR 40 mg	1	SCRN	SCREENING	Randomized to COMPARATOR 40 mg		SCREENING
COMPA	COMPARATOR 40 mg	2	PRETRT	PRE-TREATMENT			TREATMENT
COMPA	COMPARATOR 40 mg	3	COMEN	COMPARATOR			TREATMENT
COMPA	COMPARATOR 40 mg	4	POSTDOSE	POST DOSE			TREATMENT
COMPA	COMPARATOR 40 mg	5	POSTFUP	POST TREATMENT / FOLLOW-UP			POST TREATMENT OBSERVATION PERIOD

Required column
Expected column
Permissible column

TV – Trial Visits

VISITNUM	VISIT	VISITDY	TVSTRL	TVENRL	ARMCD	ARM
1	VISIT 1	-13	Informed Consent signed		abc0.3	abc-0.3 mg/kg
2	VISIT 2	1	Day 1		abc0.3	abc-0.3 mg/kg
...	...	...	...		abc0.3	abc-0.3 mg/kg
8	VISIT 8	30	Day 30 +/-5 days		abc0.3	abc-0.3 mg/kg
9	VISIT 9	90	Day 90 +/-7 days		abc0.3	abc-0.3 mg/kg
1	VISIT 1	-13	Informed Consent signed		COMPA	COMPARATOR 40 mg
2	VISIT 2	1	Day 1		COMPA	COMPARATOR 40 mg
...	...	...	...		COMPA	COMPARATOR 40 mg
8	VISIT 8	30	Day 30 +/-5 days		COMPA	COMPARATOR 40 mg
9	VISIT 9	90	Day 90 +/-7 days		COMPA	COMPARATOR 40 mg

Required column
Expected column
Permissible column

TI – Trial Inclusion/Exclusion Criteria

IETESTCD	IETEST	IECAT	IESCAT	IETEXT01	TIVERS
IN002	Patients aged >=18 years undergoing elective primary, unilateral TKA	INCLUSION			1,0
IN002	Patients aged >=18 years undergoing elective primary, unilateral TKA	INCLUSION			1,1
IN002	Patients aged >=18 years undergoing elective primary, unilateral TKA	INCLUSION			1,2
IN002A	Patients aged >=45 years undergoing elective primary, unilateral TKA	INCLUSION			1,3
IN002A	Patients aged >=45 years undergoing elective primary, unilateral TKA	INCLUSION			1,4
EX002	Prior deep vein thrombosis	EXCLUSION			1,0
EX002A	Prior deep vein thrombosis or known thrombophilic disorder	EXCLUSION			1,1
EX002	Prior deep vein thrombosis	EXCLUSION			1,2
EX002	Prior deep vein thrombosis	EXCLUSION			1,3
EX002	Prior deep vein thrombosis	EXCLUSION			1,4
EX008	Requirement for full dose anticoagulation or dual antiplatelet therapy (low dose of acetylsalicylic acid is allowed)	EXCLUSION			1,0
EX008	Requirement for full dose anticoagulation or dual antiplatelet therapy (low dose of acetylsalicylic acid is allowed)	EXCLUSION			1,1
EX008A	Requirement for full dose anticoagulation or dual antiplatelet therapy. Antiplatelets should be stopped >=7 days prior to start of study.	EXCLUSION		Requirement for full dose anticoagulation or dual antiplatelet therapy. Antiplatelets (e.g. clopidogrel, ticagrelor, dipyridamole, acetylsalicylic acid >100 mg/day) should be stopped >=7 days prior ...	1,2
EX008A	Requirement for full dose anticoagulation or dual antiplatelet therapy. Antiplatelets should be stopped >=7 days prior to start of study.	EXCLUSION		Requirement for full dose anticoagulation or dual antiplatelet therapy. Antiplatelets (e.g. clopidogrel, ticagrelor, dipyridamole, acetylsalicylic acid >100 mg/day) should be stopped >=7 days prior ...	1,3
EX008A	Requirement for full dose anticoagulation or dual antiplatelet therapy. Antiplatelets should be stopped >=7 days prior to start of study.	EXCLUSION		Requirement for full dose anticoagulation or dual antiplatelet therapy. Antiplatelets (e.g. clopidogrel, ticagrelor, dipyridamole, acetylsalicylic acid >100 mg/day) should be stopped >=7 days prior ...	1,4

Required column
Expected column
Bayer specific column

Herausforderungen

Herausforderungen

// Anzahl an TSPARMCD/TSPARM

Stand Dezember 2017	108 CDISC (bisher nicht alle von uns genutzt) + 32 Bayer spezifische Parameter

// Konditionelle Parameter

Zum Beispiel	EMPIPDCN	➔ EMA Decision Number for PIP
	EGBLIND	➔ ECG Reading Blinded
	CSRARDTC	➔ Clinical Study Report Archive Date

// Parameter mit speziellen Codelisten

Zum Beispiel	SPONSOR	➔ Clinical Study Sponsor	➔ DUNS
	COMPTRT	➔ Comparative Treatment Name	➔ UNII
	INDIC	➔ Trial Disease/Condition Indication	➔ SNOMED

Vielen Dank