ClinicalTrials.gov Registration Data Elements for Interventional Studies (DRAFT)

* required by ClinicalTrials.gov
FDAAA required to comply with PL 110-85, Section 801
(FDAAA) may be required to comply with PL 110-85, Section 801

ClinicalTrials.gov Data Element			
1. Descriptive Information			
A	Brief Title* FDAAA		
B	Brief Summary* FDAAA		
C	Primary Purpose FDAAA		
D	(Interventional) Study Design* (FDAAA)		
		Intervention Model (FDAAA)	
		Number of Arms (FDAAA)	
		Masking (FDAAA)	
		Allocation (FDAAA)	
E	Study Phase* FDAAA		
F	Study Type* FDAAA		
G	Conditions or Focus of Study* FDAAA		
H1	Intervention Type* FDAAA		
H2	Intervention Name* FDAAA		
		Intervention Description (FDAAA)	
		Arms/Groups* (FDAAA)	
		Arm Label or Number* (FDAAA)	
		Arm Type* (FDAAA)	
		Arm Description (FDAAA)	
I	Study Start Date FDAAA		
J	**Primary Completion Date** FDAAA		
K	Enrollment (Target Number of Subjects) FDAAA		
L	Primary and Secondary Outcome Measures FDAAA		
		Outcome Measure FDAAA	
		Outcome Time Frame (FDAAA)	
M		**Safety Issue? (Yes/No)** (FDAAA)	
2. Recruitment Information			
A	Eligibility Criteria* FDAAA		
B	Gender* FDAAA		
C	Age Limits* FDAAA		
D	Accepts Healthy Volunteers? FDAAA		
E	Overall Recruitment Status* FDAAA		
F	Recruitment Status (Facility)* FDAAA		
G1	Has Expanded Access? FDAAA		
G2		Expanded Access Status FDAAA	
3. Location and Contact Information			
A	Sponsor* FDAAA		
B	**Responsible Party** FDAAA		
		Name/Official Title FDAAA	
		Organization FDAAA	
		Contact Information FDAAA	

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ClinicalTrials.gov Data Element (continued)		
C1	Facility* (FDAAA)	
		Facility Name
		City* (FDAAA)
		State/Province* (FDAAA)
		Postal Code
		Country* (FDAAA)
C2	Facility Contact* (FDAAA) - or Central Contact	
		First Name
		Middle Initial
		Last Name* (FDAAA)
		Degree
		Phone* (FDAAA) - or Email
		Ext.
		Email* (FDAAA) - or Phone
C3	Central Contact* (FDAAA) - or Facility Contact	
		First Name
		Middle Initial
		Last Name* (FDAAA)
		Degree
		Phone* (FDAAA) - or Email
		Ext.
		Email* (FDAAA) - or Phone
4. Administrative Data		
A	Organization's Unique Protocol ID* FDAAA	
B	Secondary IDs FDAAA	
C1	IND/IDE Information	
		IND/IDE Protocol?* (FDAAA)
		IND/IDE Grantor* (FDAAA)
		IND/IDE Number* (FDAAA)
		IND/IDE Serial Number (FDAAA)
C2	Record Verification Date* FDAAA	
5. Other Necessary Information		
A	**Applicable Clinical Trial**	
		FDA Regulated Intervention? (FDAAA)
		Section 801 Clinical Trial? (FDAAA)
		Delayed Posting? (FDAAA)
B	**FDA Product Status** - *not yet implemented*	
C	Human Subjects Review - not required for IND/IDE or Federally funded studies	
		Board Approval*
		Board Approval Status*
		Board Approval Number*
		Board Name*
		Board Affiliation*
		Board Contact* - at least phone or email
D	Oversight Authorities* - "US FDA" if yes to IND/IDE Protocol?	
E	[NCT Number] - Assigned by ClinicalTrials.gov	
F	[First Received Date] - Assigned by ClinicalTrials.gov	