BIMO (OSI) deliverables for FDA NDA filing

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OUTLINE

- **Background of BIMO/OSI**
- **Part I item 2: Clinical Site Summary Listing**
- **Part II: Subject Level Data Listing by Site**
- **Part III: Summary Level Clinical Site (SLCS) Data**
- **Conclusion**

Background (1)

- FDA uses onsite inspections to ensure that clinical investigators, sponsors, and Institutional Review Boards (IRB) comply with FDA regulations while developing investigational drugs or biologics.

- In 1977, FDA established the **Bioresearch Monitoring** (**BIMO**) Program to develop cross-center guidelines for inspections of clinical investigators, sponsors, and IRBs.

- The BIMO Program for drugs is managed by the **Office of Scientific Investigations** (**OSI**) and for biologics by the Office of Inspections and Surveillance.

- Medical reviewers, who are responsible for approving or disapproving a product, consult with BIMO reviewers to choose which clinical trial sites to inspect.

Background (2)

- The current submission format for study-specific data in sponsors' NDA and BLA packages does not facilitate efficient site selection for FDA because these data are submitted as subject level data.
- FDA is working to modernize and enhance the efficiency and effectiveness of its inspection processes.
- FDA's **Office of Scientific Investigation (OSI)** has developed and is piloting a risk-based inspection site selection tool.
- This tool combines data from multiple databases including Summary Level Clinical Site Data to quickly analyze and assess clinical sites for identifying sites for inspection.

Background (3)

- **OSI requests sponsor to submit:**
  - **Part I: General study related information and specific Clinical Investigator Information**
  - **Part II: Subject Level Data Listings by Site**
  - **Part III: Summary Level Clinical Site Data (SLCS)**
- **Each major study (phase 2 or phase 3) should be prepared.**
- **For clinical site involved in multiple studies in support of an application, provide the data independently for each study within dataset.**

Part I: General study related information and specific Clinical Investigator Information

- Item 1: include the site information in a tabular format: site number; Principal investigator; site location (address and contact information); current location.
- Item 2: include by site information in a tabular format: Number of subjects screened; randomized; treated who prematurely discontinued.
- Item 3: include the information in a tabular format: location of Trial Master File; CROs information (name, address and contact); location of source data generated by CROs; location of study-related documents.
- Item 4: Annotated CRF.
- Item 5: Protocol and all amendments

Part I: item 2: Clinical Site Summary Listing

Clinical Site Summary Listing

Study: EFC10000

	Number of subjects		
Site	**Screened**	**Randomized**	**Treated But Prematurely Discontinued**
120001	9	7	0
120002	7	4	1
120005	13	9	0
120006	4	2	0
120007	1	1	0
120009	3	1	0
120010	8	6	3
120011	6	5	1
120016	10	5	0

Part II: Subject Level Data Listing by Site

a. Listing for each subject/number screened and reason for subjects who did not meet eligibility requirements
b. Subject listing for treatment assignment (randomization)
c. Subject listing of drop-outs and subjects that discontinued with date and Reason

d. Evaluable subjects/ non-evaluable subjects and reason not evaluable
e. By subject listing of eligibility determination (i.e., inclusion and exclusion criteria)
f. By subject listing, of AEs, SAEs, deaths and dates
g. By subject listing of protocol violations and/or deviations reported in the NDA, description of the deviation/violation

h. By subject listing of the primary and secondary endpoint efficacy parameters or events. For derived or calculated endpoints, provide the raw data listings used to generate the derived/calculated endpoint.
i. By subject listing of concomitant medications (as appropriate to the pivotal clinical trials)
j. By subject listing, of laboratory tests performed for safety monitoring

Part II:

a. Listing for each subject/number screened and reason for subjects who did not meet eligibility requirements

BIMO EFC10000 Item II - Line listing by Site

Site: 001001

a: Listing for each subject/number screened and reason for subjects who did not meet eligibility requirements

Subject Identifier	Randomized Population	Reason not eligible
010000-001-001-401	N	Not met inclusion criteria: IN04
010000-001-001-402	Y	
010000-001-001-403	Y	
010000-001-001-404	Y	
010000-001-001-405	Y	
010000-001-001-406	N	Met exclusion criteria: EX29
010000-001-001-407	N	Met exclusion criteria: EX26
010000-001-001-407	N	Not met inclusion criteria: IN04
010000-001-001-408	Y	
010000-001-001-409	Y	
010000-001-001-410	Y	
010000-001-001-411	Y	
010000-001-001-412	Y	
010000-001-001-413	N	Met exclusion criteria: EX37
010000-001-001-414	Y	

Part II:
b. Subject listing for treatment assignment (randomization)

BIMO EFC10000 Item II - Line listing by Site

Site: 001001

b: Subject listing for treatment assignment (randomization)

Subject Identifier	Treatment Assignment
010000-001-001-402	SAR123456
010000-001-001-403	Placebo
010000-001-001-404	SAR123456
010000-001-001-405	SAR123456
010000-001-001-408	SAR123456
010000-001-001-409	SAR123456
010000-001-001-410	SAR123456
010000-001-001-411	Placebo
010000-001-001-412	SAR123456
010000-001-001-414	SAR123456

Part II:
c. Subject listing of drop-outs and subjects that discontinued with date and Reason

BIMO EFC10000 Item II - Line listing by Site

Site: 001001

c: Subject listing of drop-outs and subjects that discontinued the main 24 weeks treatment period with date and reason

Subject Identifier	Treatment assignment	Reason for treatment discontinuation	Date of discontinuation	Date of last contact
010000-001-001-401	Placebo	LACK OF EFFICACY	2014-01-01	2014-01-02
010000-001-001-404	SAR123456	ADVERSE EVENT	2014-02-02	2014-03-10
010000-001-001-406	Placebo	LACK OF EFFICACY	2014-08-11	2014-08-11
010000-001-001-412	Placebo	LACK OF EFFICACY	2014-08-27	2014-09-02
010000-001-001-415	SAR123456	LACK OF EFFICACY	2014-10-26	2014-10-27
010000-001-001-417	Placebo	LACK OF EFFICACY	2014-11-16	2014-11-25
010000-001-001-418	Placebo	LACK OF EFFICACY	2015-01-11	2015-01-15

Part II:
d. Evaluable subjects/ non-evaluable subjects and reason not evaluable By subject listing of eligibility determination

BIMO EFC10000 Item II - Line listing by Site

Site: 001001

d: Evaluable subjects/non-evaluable subjects and reason not evaluable

Subject Identifier	Treatment assignment	Evaluable/Non-evaluable	Reason
010000-001-001-402	SAR123456	Y	
010000-001-001-403	Placebo	Y	
010000-001-001-404	SAR123456	Y	
010000-001-001-405	SAR123456	Y	
010000-001-001-408	SAR123456	Y	
010000-001-001-409	SAR123456	Y	
010000-001-001-410	SAR123456	Y	
010000-001-001-411	Placebo	Y	
010000-001-001-412	SAR123456	Y	
010000-001-001-414	SAR123456	Y	

Part II:
e: By subject listing of eligibility determination (i.e., inclusion and exclusion criteria)

BIMO EFC10000 Item II - Line listing by Site

Site: 001001

e: By subject Listing of eligibility determination (i.e., inclusion and exclusion criteria)

Subject Identifier	Randomized Population	Exc./Inc. Criteria Short Name	Exclusion/Inclusion Criterion
010000-001-001-401	N	IN04	Moderate-to-severely active RA.
010000-001-001-406	N	EX29	Patients with uncontrolled diabetes mellitus, defined as HbA1C >=9% at the screening visit.
010000-001-001-407	N	EX26	Exclusion criteria related to tuberculosis.
010000-001-001-407	N	IN04	Moderate-to-severely active RA.
010000-001-001-413	N	EX37	Patients with laboratory abnormalities at the screening visit (identified by the central laboratory) for Hemoglobin, WBC, Neutrophils, Platelet count, AST, ALT or Bilirubin (total).

Part II:
f: By subject listing, of AEs, SAEs, deaths and dates

BIMO EFC10000 Item II - Line listing by Site

Site: 001001

f: By subject listing, of AEs, SAEs, deaths and dates

Subject Identifier	Treatment Assignment	Treatment Received	Exposed Population	Preferred Term	Onset date /Study Day	Serious	Date of Death
010000-001-001-402	SAR123456	SAR123456	Y	Thyroid cyst	2013-10-30/D28	N	
				Heat stroke	2014-02-08/D129	N	
010000-001-001-403	Placebo	Placebo	Y	Ankle fracture	2013-12-16/D55	Y	

Part II:
g: By subject listing of protocol violations and/or deviations reported in the NDA

BIMO EFC10000 Item II - Line listing by Site

Site: 001001

g: By subject listing of protocol violations and/or deviations reported in the BLA, description of the deviation/violation

Subject Identifier	Age/Sex/Race	Treatment Assignment	Deviation	Category	Description of deviation
010000-001-00 1-403	51/F/White	Placebo	Qualitative	Laboratory/Diagnostic samples	Issues with shipping, non-compliance with regulations/IATA/protocol - Visit 7 Dir Bilirubin and HCT were not analyzed due to beyond stability.
010000-001-00 1-404	40/M/White	Sarilumab 200mg Every Other Week	Qualitative	Laboratory/Diagnostic samples	Issues with shipping, non-compliance with regulations/IATA/protocol - Visit 3 Hematology, Indirect Bilirubin, Total Abs Neutroplil count were not obtained due to beyond stability in the sample.

Should list any deviation in the study, including both Qualitative and Quantitative deviation, both Major and Minor deviations.

Part II:
h: By subject listing of the primary and secondary endpoint efficacy parameters or events.

Study : EFC10000

Site : 760001

h. By subject listing of the primary and secondary endpoint efficacy parameters or events. For derived or calculated endpoints, provide the raw data listings used to generate the derived/calculated endpoint.

Subject ID	Treatment assignment	Category	Parameter	Endpoints	Analysis Value	Baseline Value	Change from baseline	Response
760001001	SAR123456	Primary	Hemoglobin A1c	End of treatment (week 13)	6.6	7.8	-1.2	
		Secondary	Hemoglobin A1c <=6.5%	End of treatment (week 13)	6.6	7.8	-1.2	N
			Hemoglobin A1c <7.0%	End of treatment (week 13)	6.6	7.8	-1.2	Y
			Plasma glucose (random)	End of treatment (week 13)	7.8	9.5	-1.7	
			Weight in kilograms	End of treatment (week 13)	94	98	-4	

Part II:

i: By subject listing of concomitant medications

BIMO EFC10000 Item II - Line listing by Site

Site: 001001

i: By subject listing of concomitant medications (as appropriate to the pivotal clinical trials)

Subject Identifier	Treatment Assignment	Treatment Received	Indication	Medication Term	Start Medication	Dose/unit/route
010000-001-001-402	SAR123456	SAR123456	Curative	ENALAPRIL	2013-02	Oral
				ETORICOXIB	2013-02	Oral
				LEVOTHYROXINE	2001-04	Oral
				LEVOTHYROXINE	2013-11-14	Oral
				PREDNISONE	2012-04	5mg/Oral
			Prophylaxis	FEMODENE	2013-02	Oral
				FOLIC ACID	2009	Oral
010000-001-001-403	Placebo	Placebo	Curative	DICLOFENAC	2011	Oral
				DICLOFENAC	2013-12-16	Intravenous
				MEPREDNISONE	2003	8mg/Oral
				METHOTREXATE	2012	Oral

Part II:

j: By subject listing, of laboratory tests performed for safety monitoring

BIMO EFC10000 Item II - Line listing by Site

Site: 001001

j: By subject, listing of testing (e.g., laboratory, ECG) performed for safety monitoring

Patient Identifier	Treatment Received	Category	Lab Test Name*	Time Point (Result)**
010000-001-001-402	SAR123456	CHEMISTRY	Alanine Aminotransferase (IU/L)	UNS (14)/ V2 (41)/ V3 (24)/ V4 (13) V5 (17)/ V6 (17)/ V7 (18)/ V8 (12)/ V9 (15) V10 (15)/ V11 (13)
			Alanine Aminotransferase (ULN)	UNS (0.41)/ V2 (1.21)/ V3 (0.71)/ V4 (0.38)/ V5 (0.50) V6 (0.50)/ V7 (0.53)/ V8 (0.35)/ V9 (0.44)/ V10 (0.44) V11 (0.38)
			Albumin (g/L)	UNS (30)/ V2 (32)/ V3 (32)/ V4 (31) V5 (32)/ V6 (35)/ V7 (36)/ V8 (37)/ V9 (33) V10 (37)/ V11 (35)

* Only laboratory and ECG parameters of main interest have been summarized in this listing
** UNS=Unscheduled V=Visit

Part II:
Challenge

- Too big if there are too many sites in one study, e.g. >100 site.
- Unclear definition, e.g., evaluable, deviation
- Population not clearly defined
- No table shell
- Suggest to prepare any unclear information and discuss with FDA in the pre-NDA meeting

Part III:
Summary Level Clinical Site Data (SLCS)

- **CDER** issued a draft guidance relating to electronic submissions In December 2012

  Guidance for Industry: Providing Submissions in Electronic Format—Summary Level Clinical Site Data for CDER's Inspection Planning

  - **Its purpose is to assist applicants in the submission of a clinical dataset that describes and summarizes the characteristics and outcomes of clinical investigations at the level of the individual study site.**
  - **This dataset is intended to facilitate use of a risk-based approach for the timely identification of clinical investigator sites for on-site inspection by CDER during the review of marketing applications.**

- **FDA** issued technical specifications in November 2011, October 2012, and November 2012, respectively

  Specifications for Preparing and Submitting Summary Level Clinical Site Data for CDER's Inspection Planning

  - **It provides current FDA specifications for preparing and submitting a summary-level clinical-site dataset in electronic form for NDAs, BLAs, and NDA or BLA supplemental applications submitted to FDA's CDER**

Part III:
Summary Level Clinical Site Data

- **Should be provided in a single dataset containing data from all major studies used to support safety and efficacy, with totally 39 variables.**
- **Should be provided by clinical site and treatment arm for the ITT population.**
- **Should be submitted in the eCTD format belongs in Module 5 – Clinical Study Reports**
- **Should be delivered as "clinsite.xpt" with the define.pdf document**

Part III:
Summary Level Clinical Site Data

39 variables include:

- General information (Sponsor, IND/NDA/BLA number)
- Study Conduct:
  - **Enrollment**
  - **Subjects Discontinuations**
  - **Protocol Violations**
- Safety Perspective:
  - **Deaths**
  - **AEs**
  - **SAEs**
- Site-specific Efficacy
- Site Information
  - **Financial Disclosure**
  - **Name, Address and Contact information of the Primary Investigator**

Part III:
General information(Sponsor, IND/NDA/BLA number)

Variable Index	Variable Name	Variable Label	Type	Controlled Terms or Format	Notes or Description	Sample Value
1	STUDY	Study Number	Char	String	Study or trial identification number.	ABC-123
2	STUDYTL	Study Title	Char	String	Title of the study as listed in the clinical study report (limit 200 characters)	Double blind, randomized placebo controlled clinical study on the influence of drug X on indication Y
3	DOMAIN	Domain Abbreviation	Char	String	Two-character identification for the domain most relevant to the observation. The Domain abbreviation is also used as a prefix for the variables to ensure uniqueness when datasets are merged.	DE
4	SPONNO	Sponsor Number	Num	Integer	Total number of sponsors throughout the study. If there was a change in the sponsor while the study was ongoing, enter an integer indicating the total number of sponsors. If there was no change in the sponsor while the study was ongoing, enter "1."	1
5	SPONNAME	Sponsor Name	Char	String	Full name of the sponsor organization conducting the study at the time of study completion, as defined in 21 CFR 312.3(a).	DrugCo, Inc.
6	IND	IND Number	Num	6 digit identifier	Investigational New Drug (IND) application number. If study not performed under IND, enter -1.	010010
7	UNDERIND	Under IND	Char	String	Value should equal "Y" if study at the site was conducted under an IND and "N" if study was not conducted under an IND (i.e., 21 CFR 312.120 studies).	Y
8	NDA	NDA Number	Num	6 digit identifier	FDA new drug application (NDA) number, if available/applicable. If not applicable, enter -1.	021212
9	BLA	BLA Number	Num	6 digit identifier	FDA identification number for biologics license application, if available/applicable. If not applicable, enter -1.	123456
10	SUPPNUM	Supplement Number	Num	Integer	Serial number for supplemental application, if applicable. If not applicable, enter -1.	4

Part III:
Study Conduct

- **ENROLL:** Total Number of Subjects Enrolled by Treatment Arm
- **SCREEN:** Total Number of Subjects Screened
- **DISCONT:** Number of Subjects Discontinuing from the Study by Treatment Arm
- **PROTVIOL:** Number of Protocol Violations by Treatment Arm

11	SITEID	Site ID	Char	String	Investigator site identification number assigned by the sponsor.	50
12	ARM	Treatment Arm	Char	String	Plain text label for the treatment arm as referenced in the clinical study report (limit 200 characters).	Active (e.g., 25mg), Comparator drug product name (e.g., Drug x), or Placebo
13	ENROLL	Number of Subjects Enrolled	Num	Integer	Total number of subjects enrolled at a given site by treatment arm.	20
14	SCREEN	Number of Subjects Screened	Num	Integer	Total number of subjects screened at a given site.	100
15	DISCONT	Number of Subject Discontinuations	Num	Integer	Number of subjects discontinuing from the study after being enrolled at a site by treatment arm as defined in the clinical study report.	5
26	PROTVIOL	Number of Protocol Violations	Num	Integer	Number of protocol violations at a given site by treatment arm as defined in the clinical study report. This value should include multiple violations per subject and all violation type (i.e., not limited to only significant deviations).	20

Questions from the FDA's Specification

- Q1: How to handle subjects who changed the sites during the studies?
- **Answer: We count them in their original sites.**

- Q2: What treatment arm means? Planned treatment arm or actual treatment arm?
- **Answer: We used planned treatment arms in our submissions.**

- Q3: How to get the screen failure counts if the screen failure subjects were not in clinical database?
- **Answer: Provided by each study team from Clinical Operations in excel format, which was converted into a SAS dataset shown in next slide.**

- The numbers of screen failures at each site was combined with the number of subjects enrolled for the number of subjects screened at each site for SCREEN (Number of Subjects Screened at each site).

Protocol Violations – FDA's Specifications

Variable	Variable Label	Comments
PROTVIOL	Number of Protocol Violations	Number of protocol violations at a given site by treatment arm as defined in the clinical study report. This value should include multiple violations per subject and all violation type (i.e., not limited to only significant deviations).

- Should we include all violations, major ones and/or minor ones?
  - Suggest to provide all the deviations, including both Qualitative and Quantitative deviations, both Major and Minor deviations.

Part III:
Safety Perspective – FDA's Specifications

23	NSAE	Number of Non-Serious Adverse Events	Num	Integer	Total number of non-serious adverse events at a given site by treatment arm. This value should include multiple events per subject and all event types (i.e., not limited to only those that are deemed related to study drug or treatment emergent events).	10
24	SAE	Number of Serious Adverse Events	Num	Integer	Total number of serious adverse events excluding deaths at a given site by treatment arm. This value should include multiple events per subject.	5
25	DEATH	Number of Deaths	Num	Integer	Total number of deaths at a given site by treatment arm.	1

Note: **Similar to Protocol Violations,** all three variables are based on the numbers of **events**, not the numbers of **subjects**, and **are tabulated by treatment arms.**

Part III:
Efficacy Perspective

- There are four variables for the site-level efficacy results in SLCS dataset.
- OSI will use these variables to support site selection and are not intended to support evaluation of efficacy.
- The primary efficacy endpoint in the study should be used in the calculation of these variables.

Part III:
Efficacy Perspective – FDA's Specifications

16	ENDPOINT	Endpoint	Char	String	Plain text label used to describe the primary endpoint as described in the Define file included with each application (limit 200 characters).	Average increase in blood pressure
17	ENDPTYPE	Endpoint Type	Char	String	Variable type of the primary endpoint (i.e., continuous, discrete, time to event, or other).	Continuous
18	TRTEFFE	Treatment Efficacy Endpoint	Num	Floating Point	Summary statistic for each primary efficacy endpoint by treatment arm at a given site.	0, 0.25, 1, 100
19	TRTEFFS	Treatment Efficacy Endpoint Standard Deviation	Num	Floating Point	Standard deviation of the summary statistic (TRTEFFE) for each primary efficacy endpoint by treatment arm at a given site.	0.065
20	SITEEFFE	Site-Specific Treatment Effect	Num	Floating Point	Site-specific treatment effect reported using the same representation as reported for the primary efficacy analysis.	0, 0.25, 1, 100
21	SITEEFFS	Site-Specific Treatment Effect Standard Deviation	Num	Floating Point	Standard deviation of the site-specific treatment effect (SITEEFFE).	0.065
22	CENSOR	Censored Observations	Num	Integer	Number of censored observations at a given site by treatment arm. If not applicable, enter -1.	5

Four Endpoint Types--To calculate the site-specific efficacy result variable by treatment arm

From FDA's Specification

- Discrete Endpoints – endpoints based on efficacy observations that can take on a discrete number of values (e.g., binary, categorical). Summarize discrete endpoints by an event frequency (i.e., number of events), proportion of patients with an event, proportion of patients responding to treatment, or similar method at the site for the given treatment.
- Continuous Endpoints – endpoints based on efficacy observations that can take on an infinite number of values. Summarize continuous endpoints by the mean, median, or other distributional quantile of the observations at the site for the given treatment.
- Time-to-Event Endpoints – endpoints where the time to occurrence of an event is the primary efficacy measurement. Summarize time-to-event endpoints by two data elements: the number of events that occurred (TRTEFFE) and the number of censored observations (CENSOR).
- Other – if the primary efficacy endpoint cannot be summarized in terms of the previous guidelines, a single or multiple values with precisely defined variable interpretations should be submitted as part of the dataset.

Efficacy from Our Diabetes Project Submission

- **ENDPOINT=** HbA1c change from baseline to week 24
- **TRTEFFE** = For each unique STUDY, SITEID, and treatment ARM, calculate the mean HbA1c change from baseline to week 24 (CHG)
- TRTEFFS = The Standard Deviation of TRTEFFE
- **SITEEFFE** = The Difference of **TRTEFFE** between the Active treatment group and Placebo. For each unique STUDY, SITEID, and ARM except Placebo or active comparator, calculate the mean difference of primary efficacy result of investigation drug treatment arm against Placebo or active comparator
- SITEEFFS = The Standard Deviation of SITEEFFE

Derivation Rules for Site-specific Efficacy Variables in SLCS from Our Submission

- M1= mean HbA1c change from baseline to week 24 in active drug treatment arm at a given site
- M2= mean HbA1c change from baseline to week 24 in placebo or comparator arm at a given site

Variable	Derivation Rule
TRTEFFE	Equal to M1 for active drug treatment arm and M2 for placebo or comparator arm
TRTEFFS	Equal to the standard deviation of TRTEFFE.
SITEEFFE	Equal to M1-M2 Note: This variable is populated only for active drug treatment arms in SLCS.
SITEEFFS	The standard deviation of the site-specific efficacy effect size, is calculated as: $\sqrt{\frac{(n_1-1)TRTEFFS_1^2+(n_2-1)TRTEFFS_2^2}{(n_1+n_2-2)}}$ where TRTEFFSi and ni are standard deviations and sample sizes for each treatment arm. Note: This variable is populated only for active drug treatment arms in SLCS.

Part III: Investigator Information

- Name, Address and Contact information of the Primary Investigator
- Financial Disclosure
- Clinical Operations provided the information in excel format, which was converted into a SAS dataset, and was included in SLCS dataset
- Inform the project team early to have the information ready

27	FINLMAX	Maximum Financial Disclosure Amount	Num	Floating Point	Maximum financial disclosure amount ($USD) by any single investigator by site. Under the applicable regulations (21 CFR Parts 54, 312, 314, 320, 330, 601, 807, 812, 814, and 860). If unable to obtain the information required to the corresponding statements, enter -1.	20000.00
28	FINLDISC	Financial Disclosure Amount	Num	Floating Point	Total financial disclosure amount ($USD) by site calculated as the sum of disclosures for the principal investigator and all sub-investigators to include all required parities. Under the applicable regulations (21 CFR Parts 54, 312, 314, 320, 330, 601, 807, 812, 814, and 860). If unable to obtain the information required to the corresponding statements, enter -1.	25000.00
29	LASTNAME	Investigator Last Name	Char	String	Last name of the investigator as it appears on the FDA 1572.	Doe
30	FRSTNAME	Investigator First Name	Char	String	First name of the investigator as it appears on the FDA 1572.	John
31	MINITIAL	Investigator Middle Initial	Char	String	Middle initial of the investigator, if any, as it appears on the FDA 1572.	M
32	PHONE	Investigator Phone Number	Char	String	Phone number of the primary investigator. Include country code for non-US numbers.	44-555-555-5555
33	FAX	Investigator Fax Number	Char	String	Fax number of the primary investigator. Include country code for non-US numbers.	44-555-555-5555
34	EMAIL	Investigator Email Address	Char	String	Email address of the primary investigator.	john.doe@mail.com
35	COUNTRY	Country	Char	ISO 3166-1-alpha-3	3 letter ISO 3166 country code in which the site is located.	USA
36	STATE	State	Char	String	Unabbreviated state or province in which the site is located. If not applicable, enter NA.	Maryland
37	CITY	City	Char	String	Unabbreviated city, county, or village in which the site is located.	Silver Spring
38	POSTAL	Postal Code	Char	String	Postal code in which site is located. If not applicable, enter NA.	20850
39	STREET	Street Address	Char	String	Street address and office number at which the site is located.	1 Main St, Suite 100

CONCLUSION

- Provided an overview of the BIMO (OSI) package requirements for CDER's site inspection planning.
- Gave hands-on experiences from preparing BIMO (OSI) package for an NDA submission.
- We hope to make your life a little easier when you are working on preparing BIMO (OSI) package for NDA submission.

Links

- FDA OSI Slides: “Summary level data and information for CDER’s inspection planning”. http://www.fda.gov/downloads/drugs/developmentapprovalprocess/smallbusinessassistance/ucm361329.pdf

- Guidance for Industry - Providing Submissions in Electronic Format – Summary Level Clinical Site Data for CDER’s Inspection Planning http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/UCM332468.pdf

- Specifications for Preparing and Submitting Summary Level Clinical Site Data for CDER’s Inspection Planning http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/UCM332466.pdf

Questions?