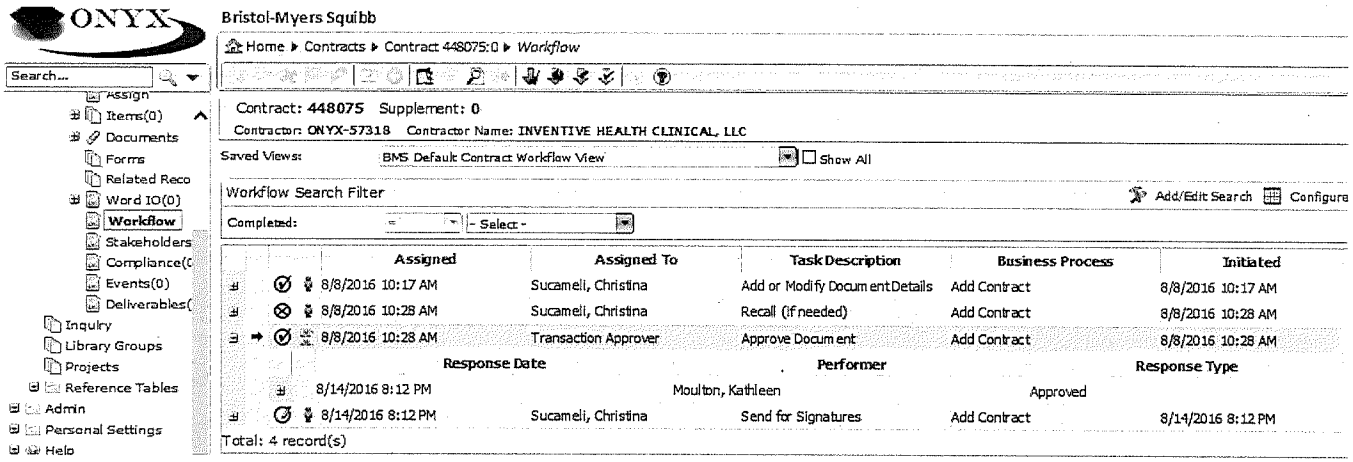
ONYX
Bristol-Myers Squibb
Home ▸ Contracts ▸ Contract 448075:0 ▸ Workflow
Search...
Assign
Items(0)
Documents
Forms
Related Reco
Word IO(0)
Workflow
Stakeholders
Compliance(
Events(0)
Deliverables(
Inquiry
Library Groups
Projects
Reference Tables
Admin
Personal Settings
Help
Contract: 448075 Supplement: 0
Contractor: ONYX-57318 Contractor Name: INVENTIVE HEALTH CLINICAL, LLC
Saved Views: BMS Default Contract Workflow View
Show All
Workflow Search Filter
Add/Edit Search
Configure
Completed:
- Select -
Assigned
Assigned To
Task Description
Business Process
Initiated
8/8/2016 10:17 AM
Sucameli, Christina
Add or Modify Document Details
Add Contract
8/8/2016 10:17 AM
8/8/2016 10:28 AM
Sucameli, Christina
Recall (if needed)
Add Contract
8/8/2016 10:28 AM
8/8/2016 10:28 AM
Transaction Approver
Approve Document
Add Contract
8/8/2016 10:28 AM
Response Date
Performer
Response Type
8/14/2016 8:12 PM
Moulton, Kathleen
Approved
8/14/2016 8:12 PM
Sucameli, Christina
Send for Signatures
Add Contract
8/14/2016 8:12 PM
Total: 4 record(s)

Eclipse Fund and Adjustment Request Sheet
Please send to CCSContracts@bms.com

Requested by*:	**Roopa Iyer**			**Date***		**08.Aug.2016**
Protocol #*	**CA 180-653**	**Fund # *** ***(if amendment)***		**Adjustment # (0= new contract)**		**0**
Financial Responsibility*	MDO/WWM/GM	**Fund Currency***	USD	**Start Event**		Contract exceuted
Contract type* (ie.CRO/CL/CS)	CRO	**Adjustment Value***	$ 444,361	**End Event**	CG = LPLV CL/CS = Final DBL CR = Final DBL/Sub Ready Report IM/ SU = FPFV DS/ IR/SS = Final LPLV	
Site # ***(CG only)***	NA	**Per Patient Cost (CG Only)**	Na	**Plan Start Date**		
Payment Frequency ***(CG only)***		**Contract # pts (CG Only)**	Na	**Comments**	Study = DM ***CG Only***: Per Patient Cost: Start up Fees: Automated payments =	
Contracted Party*	InventivHealth	**Revised # pts (CG Only)**	Na			
Vendor # (from SAP)		**ONYX # (if applicable)**				
	Vendor Contact to receive fully executed contract* (Name and Email address)	Kate Carey, kate.carey@inVentivhealth.com				

Executive Summary Narrative:

CA 180-653 is a new NIR study for Sprycel. Inventiv Health, an alliance partner, is the CRO services provider selected for this study and was selected as global CRO partner as part of the integrated Strategic Sourcing partner selection process.
The SOW details all outsourced study activities and are standard for any BMS late phase fully outsourced study.

Direct Fees	$ 381,136
Indirect Fees	$ 63,225
Start-Up SOW amount	**$ 444,361**

Required fields for processing are noted with an (*)

Ariba/Onyx Reviewers and Approvers:

Approver (as per AA table – TA Head or above): **Kathleen Moulton**

Statement Of Work-- CA180-653 Start Up Agreement

This Statement of Work (this "SOW") is made as of 1 August 2016 (the "SOW Effective Date") between **inVentiv Health Clinical, LLC** ("Provider") and **Bristol-Myers Squibb Company** on behalf of itself and its Affiliates ("BMS") under that certain Master Services Agreement (the "Agreement"), signed as of 1 November 2015 between Bristol-Myers Squibb Company and inVentiv Health Clinical LLC. Provider is an affiliated company of and successor in interest to the Agreement. The terms and conditions of the Agreement are incorporated herein by reference. In the event of a conflict between the Agreement and this SOW, the terms of the Agreement shall prevail. All capitalized terms in this SOW have the respective meanings given to them in the Agreement.

The parties hereby agree that this SOW and the Project subject hereto, incorporates all of the terms and conditions of the Agreement and is further subject to the following terms:

1. Study; Protocol Number; Research Partner (if applicable):

   Study Title: Determining Change in Cardiovascular and Metabolic Risk in Patients with Chronic Phase Chronic Myeloid Leukemia on BCR-ABL TKI Front Line Therapy

   BMS Study Drug: dasatinib/Sprycel

   Protocol Number: CA180-653

   Eudract No. (if applicable): NA

   Research Partners (if applicable):

   Territory: United States

2. SOW Term. This SOW is effective as of the SOW Effective Date and continues in full force and effect until the earlier of (a) "Acceptable completion of the Services" or (b) termination in accordance with the terms of the Agreement (the "SOW Term").

3. Project Specifications: Description of Services.

   PROVIDER shall provide the Services as set forth below, as otherwise set forth in Exhibit 1 – Project Specifications, hereto, and as set forth in the Protocol. Project Specifications may include, without limitations, Study Countries, recruitment/enrollment/randomization goals (total and/or per country), recruitment timelines, milestones, other timelines, Project assumptions and PROVIDER Personnel team structure (geographic location and management reporting structure).

4. Transfer of Obligations.

   Attached hereto as Exhibit 2 – Transfer of Obligations is the TOO, which lists the specific sponsor duties delegated by BMS to PROVIDER in connection with each study, including outlining the respective SOPs, procedures and standards to the Services performed by PROVIDER.

5. Deliverables; Acceptance Criteria.

   Project Deliverables and Acceptance Criteria will be included in the forthcoming Statement of Work and is not attached hereto.

6. Project Budget.

   The Project Budget is attached hereto as Exhibit 3 – Project Budget / Unit Definitions. BMS will pay the Project Budget to Provider in accordance with the payment terms in the Agreement.

   A high level summary of the costs associated with this SOW is:

	NA (USD)	Europe (EUR)	ROW (USD)	Global total
Direct Fees	$381,136	€0	$0	$381,136
Pass-through	$63,225	€0	$0	$63,225
Investigator Grants	$0	€0	$0	$0
Total	**$444,361**	**€**	**$**	**$444,361**
Forex rate used	€1 Euro = $ USD (N/A)			

7. Key Personnel; Project Personnel.

PROVIDER Key Personnel and their respective roles in the Project are as follows:

ROLE	NAME
Project Director	Julie Randolph
Project Manager	Jill Rogers
Scientific Affairs/Protocol Input	Sean Kennedy
Biostatistics	Amy Ryan
Medical	Joseph OConnell

8. Subcontractors

Permitted subcontractors and their respective roles in the Study are as follows:

Subcontractor	Role	Delegated Activities
NA	NA	NA

9. Project Managers; Contact Information.

BMS Project Manager:

Natane Bourne
Protocol Manager
777 Scudders Mill Road
Plainsboro NJ 08536
609-897-2522

For contract issues:

Roopa Iyer
Outsourcing Manager
Hinterbergstrasse 16,
6330 Cham, Switzerland
+41 41 767 7421

For invoicing issues:

Christine Lenio
Contracts Manager
Route 206 & Province Line Rd
Princeton, NJ 08543
609-252-6589

PROVIDER Project Manager:

Jill Rogers
Project Director
352-973-3692

For Contract issues:

Kate Carey
Senior Vice President, Business Development
1001 Winstead Drive, Suite 200
Cary, NC 27513
919-889-8897

10. List of Exhibits.

All of the following Exhibits (and those otherwise referenced in this SOW) are incorporated herein by reference and will have the effect as if fully stated in the body of this SOW.

- Exhibit 1 – Project Specifications

- Exhibit 2 – Transfer of Obligations
- Exhibit 3 – Project Budget

In order to demonstrate their agreement, the parties have executed this Statement of Work in multiple counterparts as of the SOW Effective Date.

inVentiv Health Clinical, LLC	**Bristol-Myers Squibb Company**
signature	signature
John F. Tierney	**Debra Freedholm**
printed name	printed name
Vice President	**Director, Contracts & Grants**
title	title
July 29, 2016	15 Aug 2016
date	Date

EXHIBIT 1 Study Specification **GLOBAL SUMMARY**

Study Description

	Observational Study Protocol # Ca
BMS Protocol Number	**180-653**
BMS Contact	Natane Bourne
Product Name	dasatinib (Sprycel)
Indication	Chronic Myeloid Leukemia
Study Title	Determining Change in Cardiovascular and Metabolic Risk in Patients with Chronic Phase Chronic Myeloid Leukemia on BCR-ABL TKI Front Line Therapy
Countries	Participating countries : USA
Proposal Requesting Date	01 August 2016

	Date	Parameter	Unit	Comments
Study Start Date	1-Sep-16			Start Date of earliest CRO involvement in all geographies. Please note: first 3 months for project management includes protocol development, site feasibility, and CRF development. Protocol input needed earlier.
First Site Initiation Date	1-Nov-16			Final protocol must be in place by 1 Sep 2016 to achieve FSI date; assumes FSI will meet IRB/contract timelines in < 2 mos
FPFV	1 Jan 17	4.0	Months	As 1 Jan17 is a US holiday, FPFV will need to be in late Dec or after 1 Jan 2017. . Final timeline will be addressed in full SOW once the inVentiv and BMS study teams align on key study milestone dates..
CRO Responsible for Start-Up		Y	Y/N	For SUA activities described below
CRO Responsible for Pre-study Activities		Y	Y/N	For SUA activities described below

Detailed Study Specification for SUA Activities

I. Start-up/Pre-Study Activities	**Unit Type**	**Unit Number / Parameter**	**Comments**
Protocol Preparation	Protocol	Y	inVentiv to provide protocol review and support
Kick-off Meeting (F2F)	Meeting	1	inVentiv attendees include Project Manager, Lead CRA, Contracts Associate, Regulatory Associate, Data Manager, Biostatistician, Project Director
Project Management	Months	3	For PM and LCRA (PMOL); 3 each / 6 total units

Site Identification	Sites Contacted	50	BMS expects 12 sites to participate and has specified up to 50 sites will be targeted initially to assess interest / suitability for participation. inVentiv recommends that BMS and inVentiv discuss expected total sites to participate given 18 month recruitment period and recent recruitment rates of 0.11 patients / site / month.
Site Identification	CDA Sent	30	As specified by BMS.
Site Identification	CDA Executed/Site Assessment Sent	30	As specified by BMS.
Pre-study Visit (remote)	Visit (1 hr phone call)	18	Assume 6 sites involved in IRB / contract activities may decline participation; expect 18 sites in PSV activities to yield 12 sites BMS included in preliminary RFP. As noted above, inVentiv recommends discussion on site requirements.
IRB Central	Site	4	
IRB Local	Site	9	1 unit for central IRB package preparation and submission activities prior to individual site / PI submissions; remaining 8 units for sites requiring local IRB
Site Agreement Set-up	Country (US)	1	Based on BMS NIR template; includes contract language and budget template parameters agreed between inVentiv and BMS
Site Agreement	Contract	12	Customized for site-specific requirements
Country-specific ICF	Country (US)	1	Based on BMS NIR template
Informed Consent	Site	13	Customized with site-specific requirements
Study Packages	Site	3	Includes inVentiv regulatory review / 'green light' approval required prior to site initiation (SIV)
Initiation Visits	Visit (2 hr remote)	3	SIVs
Investigator Grant Management	Payment	12	For IRB and / or site start-up payments required during site recruitment phase
Project Management Fixed	Study	1	Study planning, plan development, and study-specific training for inVentiv staff
Data Management Plan	Plan	1	
Database Design	Unique CRF Page	20	Based on BMS estimate of 20 unique pages; actual CRF units will be reconciled in the full SOW

Database Design	Repeat CRF Page	56	inVentiv assumes 56 repeat CRFs based on 20 uniques and current draft assessment schedule; total of 76 CRFs per casebook (per patient)
Database Design	Database	1	Database programming and validation
UAT	Unique CRF Page	20	Assumes BMS will provide one round of UAT review feedback
Electronic Study File Set-up	Per Site	12	12 sites expected per BMS
External Team Meetings (remote)	Meeting	12	Weekly
Internal Team Meetings (remote)	Meeting	12	Weekly

EXHIBIT 2. TRANSFER OF OBLIGATIONS (FULL SERVICE OUTSOURCING)

Sponsor:	**Bristol-Myers Squibb Company**
CRO:	**inVentiv Health**
Protocol:	**Observational Study Protocol # CA180-653**
Date:	**01 August 2016**

		Responsibility		**Comments** – note iHC intentionally left reference numbers to align with those in 'master' ToO.
Ref.	**Task**	**BMS**	**CRO**	
1	**Study Design**			
1.1	Protocol and Amendment Development	x	(x)	BMS is responsible for overall protocol development, inVentiv will review and provide input on protocol per BMS request
1.2	Design and Development of Study Documentation	x	x	For example, informed consent and site contract (CRO to use BMS templates and adhere to the BMS Core Principles)
3	**Study Initiation**			
3.2	Submission to Ethics Committees/IRBs		x	iHC to prepare and submit, or assist the sites to do the same as appropriate, all documentation
3.3	Site Identification/ Site Assessment		x	iHC will initiate site contact to assess interest and suitability for study. Includes development of Site Assessment Questionnaire, provision of CDA and draft Synopsis to potential sites, collecting CDAs from sites, and collection of completed Site Assessment Questionnaire. Site responses will be maintained in a tracking tool by iHC.
3.4	Site Selection	x	x	BMS to confirm if it will provide iHC with initial potential site list. iHC to perform site qualification activities. BMS Affiliates to review and approve if additional sites proposed by iHC within 5 business days.
3.5	Develop Site Budget	x	x	BMS and iHC will mutually develop site budget based on level of site effort commensurate with level of work and BMS guiding principles. Historical references for similar BMS studies to be used as a baseline.

3.6	Site Agreements		x	BMS country specific CTA and CDA templates will be used. Minimal contract negotiations are assumed. Negotiations by iHC shall be within BMS Core Principles, items requested by sites outside of that will require BMS approval.
4	**Study Conduct**			
4.1a	Study Site Initiation		x	SIVs will be performed remotely; since no drug shipment is required for this NIR study, SIVs are performed once all essential documents have been received by iHC and reviewed for completeness.
4.1b	Study Package Distribution		x	Site-specific study binders will be prepared and distributed to site for remote SIV, including standard study documentation and site-specific documents (e.g. site ICF template).
4.1d	Collect and review study documents		x	iHC will be responsible for the collection, review and approval of all Clinical Trial Package documents prior to the SIV. Documents will be stored in iHC's eTMF and transferred to BMS at the end of the study. BMS will not review documents or approve sites for initiation.
4.1e	Activate sites when ready for enrollment		x	Per iHC procedures, sites are SIV'd at the time when all start-up activities have been completed, and are therefore 'activated' at the time of SIV. Exceptions to this must be managed on a case by case basis and documented as deviations to iHC procedures.
4.1f	Create site files suggest changing this to 'TMF set-up' (to be consistent with unit grid)		x	iHC will set-up eTMF files for each site.
5	**Study Management**			
5.1	Project Management		x	Project management activities are defined as the FTE units for Project Manager (PM) and Lead CRA (LCRA); all time allocated for study involvement across activities for these resources are defined by the FTE allocations. Study team meetings and other PM-related activities for team members beyond the PM and LCRA are defined in the 'below the line item' units
5.1j	Produce initial Project Plan and updates		x	Project plans to be developed during initial study start-up period and updated annually or as deemed appropriate based on significant changes required.
7	Data Management			
7.2	eCRF design/CRF design	input	x	eCRFs will be developed collaboratively based on protocol requirements and publication strategies. inVentiv assumes two rounds of review and comment for BMS.
7.3	Database Design		x	Developed simultaneously with CRF design in RAVE. UAT will be performed by iHC; BMS may participate as desired. It is assumed BMS will provide one round of review for UAT.

Exhibit 3 Project Budget **Currency:** USD $ **GLOBAL SUMMARY**

ACTIVITY	UNIT	UNIT PRICE	No. Units	Activity Cost	Pass Thru Cost	TOTAL COST
Start-Up Activities						
IRB Central (US only)	Central IRB (Sites)	$1,015	4	$4,060	$4,100	$8,160
IRB / EC (Local)	Local IRB (Site)	$1,450	9	$13,050	$13,775	$26,825
Subtotal				**$17,110**	**$17,875**	**$34,985**
Study Management						
Investigator Grant Management	Per Payment	$66	12	$792	-	$792
Manager 0.5 FTEs*	Monthly (78 hours per month)	$15,522	3	$46,566	-	$46,566
Lead CRA 0.75 FTEs	Monthly (116 hours per month)	$22,620	1	$22,620	-	$22,620
Lead CRA 0.5 FTEs	Monthly (78 hours per month)	$15,210	2	$30,420	-	$30,420
Project Management Fixed (medium)	Study	$15,263	1	$15,263	-	$15,263
Subtotal				**$115,661**	**-**	**$115,661**
Pre-Study Activities						
Site Agreement Set up	Country	$1,680	1	$1,680		$1,680
Site Agreement	Per Contract	$1,514	12	$18,168		$18,168
Country-Specific ICF	Per Country	$435	1	$435		$435
Informed Consent	Per Site (Simple, e.g. Central IRB/EC, Assent)	145	4	$580	-	$580
Informed Consent	Per Site (Medium, e.g. Local IRB/EC)	$435	9	$3,915	-	$3,915
Study Packages	Site	$1,665	3	$4,994	-	$4,994
Site Identification	Site Contacted	$73	50	$3,625		$3,625
Site Identification	CDA Sent	$73	30	$2,175		$2,175
Site Identification	CDA Executed/Site Assessment Sent	$145	30	$4,350		$4,350
Pre-Study Visit (remote)	Visit (1hr phone call)	$506	18	$9,099		$9,099

ACTIVITY	UNIT	UNIT PRICE	No. Units	Activity Cost	Pass Thru Cost	TOTAL COST
Subtotal				**$49,021**		**$49,021**
Initiation Activities						
Initiation Visits	Visit (2hr Remote)	$578	3	$1,734		$1,734
Subtotal				**$1,734**		**$1,734**
Data Management						
Data Management Plan	Plan (Complex)	$16,365	1	$16,365		$16,365
Database Design	Per Unique CRF Page	$3,315	20	$66,300		$66,300
Database Design	Per Repeat CRF Page	$393	56	$22,027		$22,027
Database Design	Per Database	$4,320	1	$4,320		$4,320
Database Design	Per CRF	$190	76	$14,440		$14,440
UAT	Per Unique CRF Page	$1,658	20	$33,150		$33,150
EDC Pass-through Cost	Pass-through only				$35,750	$35,750
Subtotal				**$156,602**	**$35,750**	**$192,352**
Other Activities						
Electronic Study File Set-up	Per Site	$63	12	$750		$750
Subtotal				**$750**		**$750**
Project Specific - below the line						
Kick-off Meetings (on-site)	Meeting	$16,884	1	$16,884	$9,600	$26,484
External Team Meetings (remote)	Meeting	$759	12	$9,108		$9,108
Internal Team Meetings (remote)	Meeting	$1,007	12	$10,647		$10,647
Protocol Preparation	Protocol	$3,620	1	$3,620		$3,620
Subtotal				**$41,700**	**$9,600**	**$49,859**
TOTALS (Excluding Grants)				**$381,136**	**$63,225**	**$444,361**
Inflation						
Total Investigator Grants						
PROJECT TOTAL				**$381,136**	**$63,225**	**$444,361**

Global Summary In Native Currency	$USD
Activity Costs	$381,136
Pass Thru Costs	$63,225
Investigator Grants	$0
Grand Total	**$444,361**