

# OnCore: Clinical Trials Management

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Information Services

# Overview

- What is OnCore CTMS?
- What are the intended integrations?
- How does this meet enterprise goals?
- What is the unique nature of being dual institutional?
- When will it be ready?
- Electronic Data Capture

# What is OnCore?

- Clinical Trials Management System
- Protocol Management
  - What does the calendar dictate ?
- Subject Management
  - In which trial is the participant enrolled?
- Financials/Invoices Management
  - Which grants are linked to which sponsors?
- Reporting

# Protocol Submission

Protocol Console (PC)  
Includes protocol general info, study team, sponsor(s), IND/IDE information, and exportable Clinical Trials.gov file to upload directly to website

★ PC Console ?

Protocol No.: **RXDX-101-01**      Library: **Oncology**      PI:      Sponsor: **Ignyta, Inc.**  
 Protocol Target Accrual: **8**      Accrual To Date: **5**      Protocol Status: **OPEN TO ACCRUAL**  
 RC Total Accrual Goal (Upper): **8**

Select Protocol  
[Type here to search: ▼]

Main

»

Treatment

»

Institution

»

Accrual

»

Status

»

Reviews

»

Documents/Info

»

Eligibility

»

Protocol Calendar

»

Notifications

»

Conclusions

»

Deviations

»

New Protocol

»

Details
Management
Staff
Sponsor
IND/IDE
ClinicalTrials.gov / CTRP

History

Protocol No. RXDX-101-01		NCT Number NCT02097810	
Library Oncology		Department Oncology	
Organizational Unit USC Oncology			
Title A PHASE 1/2A, MULTICENTER, OPEN-LABEL STUDY OF ORAL RXDX-101 IN ADULT PATIENTS WITH LOCALLY ADVANCED OR METASTATIC CANCER CONFIRMED TO BE POSITIVE FOR TRKA, TRKB, TRKC, ROS1, OR ALK MOLECULAR ALTERATIONS			
Short Title FP00004305 0C-14-7: P1/2a of Oral RxDx-101 for Adv or Met CA			
Objectives Entrectinib (previously known as RXDX-101) is an orally available inhibitor of the tyrosine kinases TrkA, TrkB, TrkC, ROS1, and ALK. Molecular alterations to one or more of these targets are present in several different tumor types, including non-small cell lung cancer (NSCLC), colorectal cancer (CRC), prostate cancer, papillary thyroid cancer, pancreatic cancer, and neuroblastoma. Patients with locally advanced or metastatic cancer with a detectable molecular alteration in targets of interest may be eligible for enrollment.			
Phase 1 will assess safety and tolerability of entrectinib via standard dose escalation scheme and determine the recommended Phase 2 dose.			
Phase 2 will assess treatment efficacy and safety of entrectinib.			
Phase	III	Scope	National
Age	Adults	Consent at Age of Majority	N/A
Drug Accountability	Yes	Investigator Initiated Protocol	No
Involves Therapy	Yes	Exclude Protocol on Web	No
Open For Affiliates Only	No	Summary Accrual Info. Only	No
Protocol Type		Treatment	
Cancer Control	No	Cancer Prevention	No
Data Table 4 Report Type		Interventional	
Registration Center	Research Center	Involves Correlates or Companions	No
Data Monitoring	DSMC	Adjuvant	
Includes Specimen Banking?	No	Companion Study?	No
Multi-site Trial	Yes	Investigational Drug	Yes
Investigational Device		No	

Accrual Information			
Protocol Target Accrual	8	RC Total Accrual Goal (Lower)	
RC Annual Accrual Goal		Affiliate Accrual Goal	
		RC Total Accrual Goal (Upper)	8
		Accrual Duration (Months)	24

Completion Dates	
Primary Completion Date	06/30/2016 (Anticipated)
Study Completion Date	06/30/2016 (Anticipated)

Update

Lock Protocol

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# Budget Created From Visits + Fees

Study Calendar lays foundation to complete coverage analysis assessment and attribute other study related fees

**Coverage Analysis Console**

Contract No.: Protocol No.: RXDX-101-01 Library: Oncology Sponsor: Ignyta, Inc.  
 Protocol Target Accrual: 8 RC Total Accrual Goal (Upper): 8 Ac accrual To Date: 5  
 Short Title: FP00004305 0C-14-7: P1/2a of Oral Rx/Dx-101 for Adv or Met CA Status: OPEN TO ACCRUAL

Select Protocol: Type here to search  
 Billing Grid Display Filters: Calendar Version: V4 (06/10/2015) Budget Version: 1 (06/10/2015) Sponsor: Billing Designation Filter: Multi-Select Display Event Codes and Item Codes:  Clear Refresh

Freeze Panes

Arm: 1:1 Version: V4 (06/10/2015)

Treatment	Cycle 1														Cycles 2+												Follow Up				Comments
	Screen	C1D1	C1D7	C1D14	C1D21	C1D28	C1D35	C1D42	C2D7	C2D14	C2D21	C2D28	C3D14	C3D28	C4D14	C4D28	C5D14	C5D28	C6D14	C6D28	End of Tx	Survival	Follow-Up	Follow-Up							
	D1	D7	D14	D21	D28	D35	D42	D7	D14	D21	D28	D14	D28	D14	D28	D14	D28	D14	D28	D14	D28	D1	M3	M6	M9	M12					
Informed Consent	NB																														
Eligibility Assessment <sup>b</sup>	R	R																													
Physical Exam	S	S	S	S	S	S	S	S																							
Molecular Characterization of Tumor	R																														
Serum Pregnancy Test	R							R				R	R	R	R	R	R	R	R	R	R										
Clinical Safety Laboratory Tests	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R					
ECOG Performance Status	R	R					R					R	R	R	R	R	R	R	R	R											
Vital Signs	R	R	R	R	R	R	R	R				R	R	R	R	R	R	R	R	R	R	R	R	R	R	R					
12-Lead ECG	3R	3R	3R					3R				3R		3R	3R	3R	3R	3R	3R	3R	3R										
Tumor Biopsy	R				R																										
Tumor Imaging	R							R							R							R									
Enrollment	R																														
RXDX-101 Dispensation		R						R				R	R	R	R	R	R	R	R	R	R										
PK Assessment		3R	2R	3R		3R	R	3R				R	R	R	R	R	R	R	R	R	R										
PD Assessment		3R	2R	2R		2R						R	R	R	R	R	R	R	R	R	R										
CGF Assessment																															
RXDX-101 Accountability			R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R					
Concomitant Medications	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R					
Adverse Events		R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R					
24 Hour Urine Collection		R																													
Drug administration	R																														
Imaging	3R	3R	3R					3R	3R						3R	3R	3R	3R	3R	3R	3R										
CTU Additional Clinical Time - 5min/0.05	R																														

Expand All Collapse All

Foot Notes

Index	Footnote
	* Budget only procedure/item
	b. Includes review of medical/oncologic history and inclusion/exclusion criteria

# Budget Summary

- Ability to review overall budget in multiple format
- Exportable to excel/pdf
- Ability to assess budget (starting point of negotiation, finalized, updates related to amendments)

Admin | Adults / monitoring | eCRs / eCRs | eCRs | Financials | My Console | Protocols | Reports | Reviews

### Budget Comparison

Contract No.: Protocol No.: RXDX-101-01 Library: Oncology Sponsor: Ignyta, Inc.  
 Protocol Target Accrual: 8 PI: Accrual To Date: 5  
 RC Total Accrual Goal (Upper): 8  
 Short Title: FP00004305 0C-14-7: P1/2a of Oral RxDx-101 for Adv or Met CA Status: OPEN TO ACCRUAL

	Original Research Cost	Current Research Cost	Protocol Cost		% Change	Estimated Cost ***	
				With Indirect & Overhead			With Indirect & Overhead
<b>Startup Charges</b>	\$0.00	\$0.00	\$3,050.00	\$3,125.00			
<b>Per Subject Charges</b>							
<b>Arm 1: 1</b>	\$0.00	\$0.00	\$7,296.82	\$7,496.02		\$7,296.82	\$7,496.02

\* Research Costs from the Charge Master.  
 \*\* Calculated based on Original Research and Current Research costs.  
 \*\*\* Change in research costs applied to Protocol costs.

Export

Back to: Protocol Budget Criteria

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### Protocol Budget Summary

Contract No.: Protocol No.: RXDX-101-01 Library: Oncology Sponsor: Ignyta, Inc.  
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 Short Title: FP00004305 0C-14-7: P1/2a of Oral RxDx-101 for Adv or Met CA Status: OPEN TO ACCRUAL

#### Startup Charges

Event	Negotiated Charge
IRB Preparation Fee	\$300.00
IRB Startup Fee (IRB Submission Fee)	\$2,150.00
IRB Startup Fee (Translation Fee)	\$600.00
<b>Total Startup Charges</b>	<b>\$3,050.00</b>

#### Per Subject Charges (Based on one (1) subject on Arm 1: 1)

Version: V4 (06/10/2015)

Event	Negotiated Charge	Milestone		Regular Pass Thru		As Needed Pass Thru	
		No. per Subject	Total	No. per Subject	Total	No. per Subject	Total
Informed Consent	\$0.00	0	\$0.00	0	\$0.00	0	\$0.00
Eligibility Assessment	\$0.00	2	\$0.00	0	\$0.00	0	\$0.00
Molecular Characterization of Tumor	\$0.00	1	\$0.00	0	\$0.00	0	\$0.00
Serum Pregnancy Test	\$99.00	8	\$792.00	0	\$0.00	0	\$0.00
Clinical Safety Laboratory Tests	\$0.00	21	\$0.00	0	\$0.00	0	\$0.00
ECOG Performance Status	\$0.00	8	\$0.00	0	\$0.00	0	\$0.00
Vital Signs	\$0.00	14	\$0.00	0	\$0.00	0	\$0.00
12-Lead ECG	\$300.00	42	\$12,600.00	0	\$0.00	0	\$0.00
Tumor Biopsy	\$0.00	3	\$0.00	0	\$0.00	0	\$0.00
Tumor Imaging	\$1,300.00	5	\$6,500.00	0	\$0.00	0	\$0.00
Enrollment	\$0.00	1	\$0.00	0	\$0.00	0	\$0.00
RXDX-101 Dispensation	\$0.00	7	\$0.00	0	\$0.00	0	\$0.00
PK Assessment	\$0.00	40	\$0.00	0	\$0.00	0	\$0.00
PD Assessment	\$0.00	15	\$0.00	0	\$0.00	0	\$0.00
CSF Assessment	\$50.00	0	\$0.00	0	\$0.00	0	\$0.00
RXDX-101 Accountability	\$0.00	19	\$0.00	0	\$0.00	0	\$0.00
Concomitant Medications	\$0.00	26	\$0.00	0	\$0.00	0	\$0.00
Adverse Events	\$0.00	25	\$0.00	0	\$0.00	0	\$0.00
24 Hour Urine Collection	\$0.00	1	\$0.00	0	\$0.00	0	\$0.00
Drug administration	\$100.00	3	\$300.00	0	\$0.00	0	\$0.00
Imaging	\$0.00	0	\$0.00	11	\$0.00	0	\$0.00
* CTU Additional Clinical Time - 5min/0.08	\$4.82	1	\$4.82	0	\$0.00	0	\$0.00
<b>Total Per Subject Charges</b>			<b>\$20,196.82</b>		<b>\$0.00</b>		<b>\$0.00</b>

\* Budget only procedure/item

Export

Back to: Protocol Budget Criteria

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# Subject Tracking & Invoicing

**CRA Console** Protocol No.: RXDX-101-01 Library: Oncology Accrual To Date: 5 Sponsor: Igenya, Inc. Protocol Status: OPEN TO ACCRUAL

RC Total Accrual Goal (Upper): 8  
Short Title: FPO0004305 OC-14-7: P12a of Oral Rx Dx-101 for Adv or Met CA

Select Protocol [Type here to search] Accrued

Select Subject [Type here to search]

Accrual Details Page Size: 10

Study Site	Research ID	Last Name	First Name	Site No.	Act	Level	Status	Status Date	Vis	Last Visit	Select	
Keck Hospital of USC	11-1234	On	Core	12345678	1		ELIGIBLE	06/09/2015	3	C1D1	06/09/2015	<input type="checkbox"/>
Keck Hospital of USC	11-5555	Taite	Fan		1		ON TREATMENT	06/09/2015	3	C1D14	06/09/2015	<input type="checkbox"/>
North Comprehensive Cancer Center	11-6666	Jones	Joe	12121212	1		ON TREATMENT	06/11/2015	4	Screen	06/11/2015	<input type="checkbox"/>
Keck Hospital of USC	23875624	Volia	Sara		1		ON TREATMENT	04/05/2015	4	Screen	04/02/2015	<input type="checkbox"/>
Keck Hospital of USC	44321	Test	Tester		1		ON TREATMENT	04/18/2015	3	C1D1	04/18/2015	<input type="checkbox"/>

Switch Calendar Versions: 1 | Replace Versions | Select All | None | Accrual

Include Print | View PDF | Save Preferences

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**Subject Console** Protocol No.: RXDX-101-01 Protocol Status: OPEN TO ACCRUAL Subject Name: Core On

Research ID: 11-1234

Calendar [Dignified Visits]

Freeze Dates | Full Calendar | Current Subject Calendar Version: 13

Procedure Study Calendar	Treatment										
	Cycle 1 1/06/15 @ 03/05/15	2	3	4	5	6	7	8	9	10	11
Eligibility	X										
On Study	X										
Treatment											
Follow-up											
SAEs											
Eligibility Assessment <sup>1</sup>	X										
Physical Exam	X	X	X	X	X	X	X	X	X	X	
Molecular Characterization of Tumor											
Serum Pregnancy Test								X			
Clinical Safety Laboratory Tests	X	X	X	X	X	X	X	X	X	X	X
ECOG Performance Status	X							X			
Visit Signs	X	X	X	X	X	X	X	X	X	X	
12-Lead ECG	SK	SK									SK
Tumor Biopsy							X				
Tumor Imaging								X			
Enrollment									X		
RXDX-101 Dispensation	X								X		
PK Assessment	SK	2K	SK				SK	X	SK		
PD Assessment	SK	2K	2K				2K				
CSF Assessment											
RXDX-101 Accountability	X	X	X	X	X	X	X	X	X	X	X

**Financials Console** Contract No.: Protocol No.: RXDX-101-01 Library: Oncology Accrual To Date: 5 Sponsor: Igenya, Inc. Protocol Status: OPEN TO ACCRUAL

RC Total Accrual Goal (Upper): 8  
Short Title: FPO0004305 OC-14-7: P12a of Oral Rx Dx-101 for Adv or Met CA

Select Protocol [Type here to search] Invoice No: 1 Invoice Date: 05/27/2015

Parameters

Budget

Protocol Related

Subject Related

Receivables

Event	Detail	Occurred Date	Amount		Total After Withheld?	Paid?	Due?	With-off	Comments
			Direct <sup>1</sup>	Total <sup>2</sup>					
IRB Preparation Fee			300.00	375.00	N	375.00	9.99	365.01	

Invoice Total (including Indirect Costs @ 25.0% and Overhead Costs @ 0.0%): 375.00  
Total Due After Withheld: 375.00

Invoicing Rules

Check No.	Amount	Payment Date
1516	5.00	05/27/2015
11142	120.23	06/03/2015

Invoice Comments

1 Indirect and overhead charges not included  
2 Includes indirect (if applicable) and overhead charges  
3 Payment made against item  
4 Amount due after payment and write-off

View Excel | View PDF | Update

Choose template: Sponsor Invoice | PDF | Run Report

Budget Compare | Budget Summary | Budget Calendar

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Keck Medicine of USC

BEYOND EXCEPTIONAL MEDICINE™

# USC/CHLA Scope

# USC/CHLA Scope

- ONE (1) instance of the application between the USC entities (Keck + all schools) and CHLA
- Covers (initially) all human studies that require billable performed clinical service
- Others can be added later
- Includes Industry, Federal Cooperative Group, Federal individual and Investigator Initiated Trials

# Integrations

# Integration 1 – iSTAR/IRB

- Common study number between iStar and CTMS
- IRB approval date
- IRB Study Status
- Design decision NOT complete
  - Whether scientific review is completed in iStar or in OnCore (EPRMS workflow tool)
- Application interface is purchased and will be programmed as part of phase 1

## Integration 2 – Research ID/Cerner

- The dual institution master patient index (MPI) (from the two instances of Cerner) **FEEDS** the CTMS with all potential participants (merges duplicates)
- The CTMS **FEEDS** the respective electronic health records with the compendium of all studies and the participant enrollment (along with status—eligible, on study, off study)

# Integration 3 – Financials

- At USC: once a study is “launched” (IRB review initiated) KC is launched to allow for appropriate grant/contract mgmt
- CTMS only “keeps track” of the grant linked to the sponsor but does not replace KC/KFS integration where grant → fund account.
- KC/KFS are the “master” systems
- Live feed NOT recommended for Phase 1

## Integration 3 – Financials, con't

- At CHLA, the “master” of the fund account is Peoplesoft
- Makes excess complexity in the initial phase to attempt two live feeds
- The bulk of the invoice/payment management can occur within OnCore, and the totals applied back to the respective general ledgers
- Endorsed by operational project team

**When will it be ready?**



# Pilot Go-Live: End of Summer 2015

USC:

End of Summer 2015 Go-Live OnCore Modules:

- Protocol Console
- Subject Console
- Finance Console
- Integrations – iSTAR, community MRN (Demographics ADT feed), Keck Cerner
- User Authentication (LDAP) – CHLA & Keck

Out of Scope for Initial Pilots:

- ePRMS – limited functionality (need clearer definition of feasibility to broaden use of module)
- FORMS/EDC module(s)
- Non Keck/CHLA/LAC clinical research study participants
- Integration with Quali/KFS and/or CHLA financial systems (PeopleSoft) biorepository, and registry modules

# Electronic Data Capture

# Why change anything?

- Keeping data in various forms poses privacy and security risks and requires additional manual effort
- New tools exist that are tailored to multiple research situations AND allow for interfacing of data from clinical trials management systems

# The complex trial

- Historical/Current : Café Patients
  - Managed by Norris Cancer Center
  - Powerful
  - Integrates with Café protocols
- Future: iMedidata Rave
  - Subsidized by NCI
  - Avail for cancer/non-cancer
  - Two year migration to the new standard

# The mid range to simple trial

- Historical/Current
  - RedCap: sponsored by SC-CTSI
  - Excel 😞
- Future:
  - RedCap
  - OncoreForms: excellent integration to clinical trials management
  - Two year migration to the added standard
- Retire Excel 😊

# Questions