Keck Medicine of USC

BEYOND EXCEPTIONAL MEDICINE

OnCore: Clinical Trials Management

Josh Lee, MD

Information Services

Overview

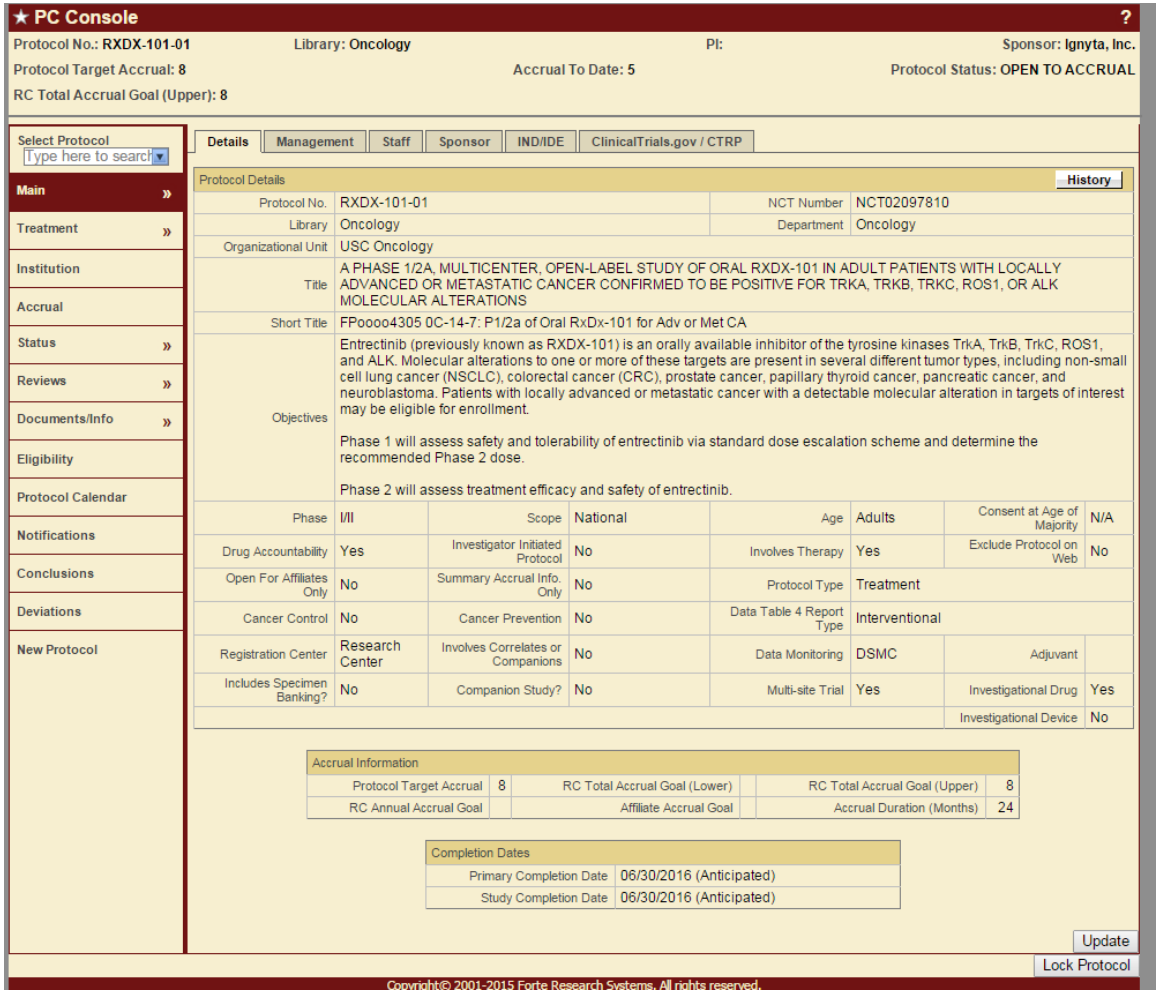
- What is OnCore CTMS?
- What are the intended integrations?
- How does this meet enterprise goals?
- What is the unique nature of being dual institutional?
- When will it be ready?
- Electronic Data Capture

What is OnCore?

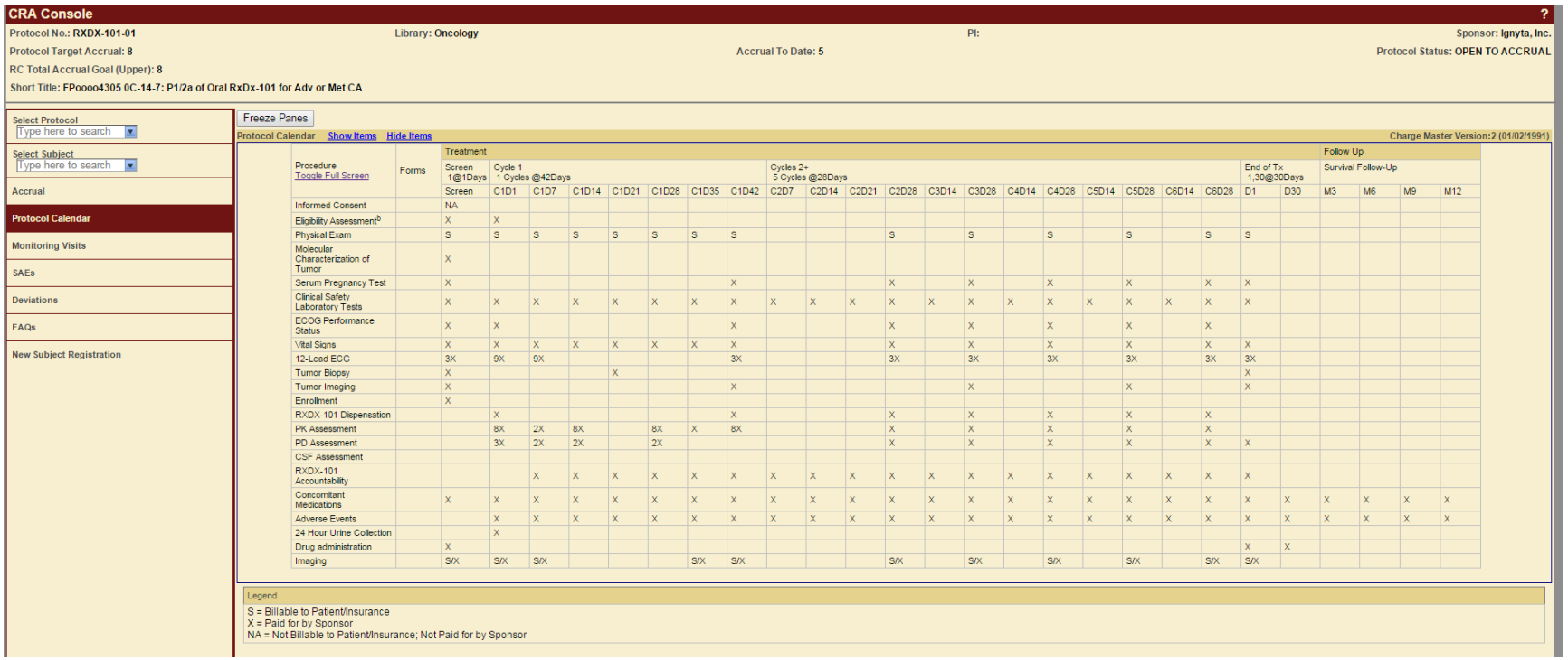
- Clinical Trials Management System
- Protocol Management
  - What does the calendar dictate ?
- Subject Management
  - In which trial is the participant enrolled?
- Financials/Invoices Management
  - Which grants are linked to which sponsors?
- Reporting

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



Study Calendar



CRA 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**

Short Title: **FPoooo4305 0C-14-7: P1/2a of Oral RxDx-101 for Adv or Met CA**

Select Protocol — Type here to search

Select Subject — Type here to search

- Accrual
- **Protocol Calendar**
- Monitoring Visits
- SAEs
- Deviations
- FAQs
- New Subject Registration

Freeze Panes

Protocol Calendar — Show Items — Hide Items — Charge Master Version:2 (01/02/1991)

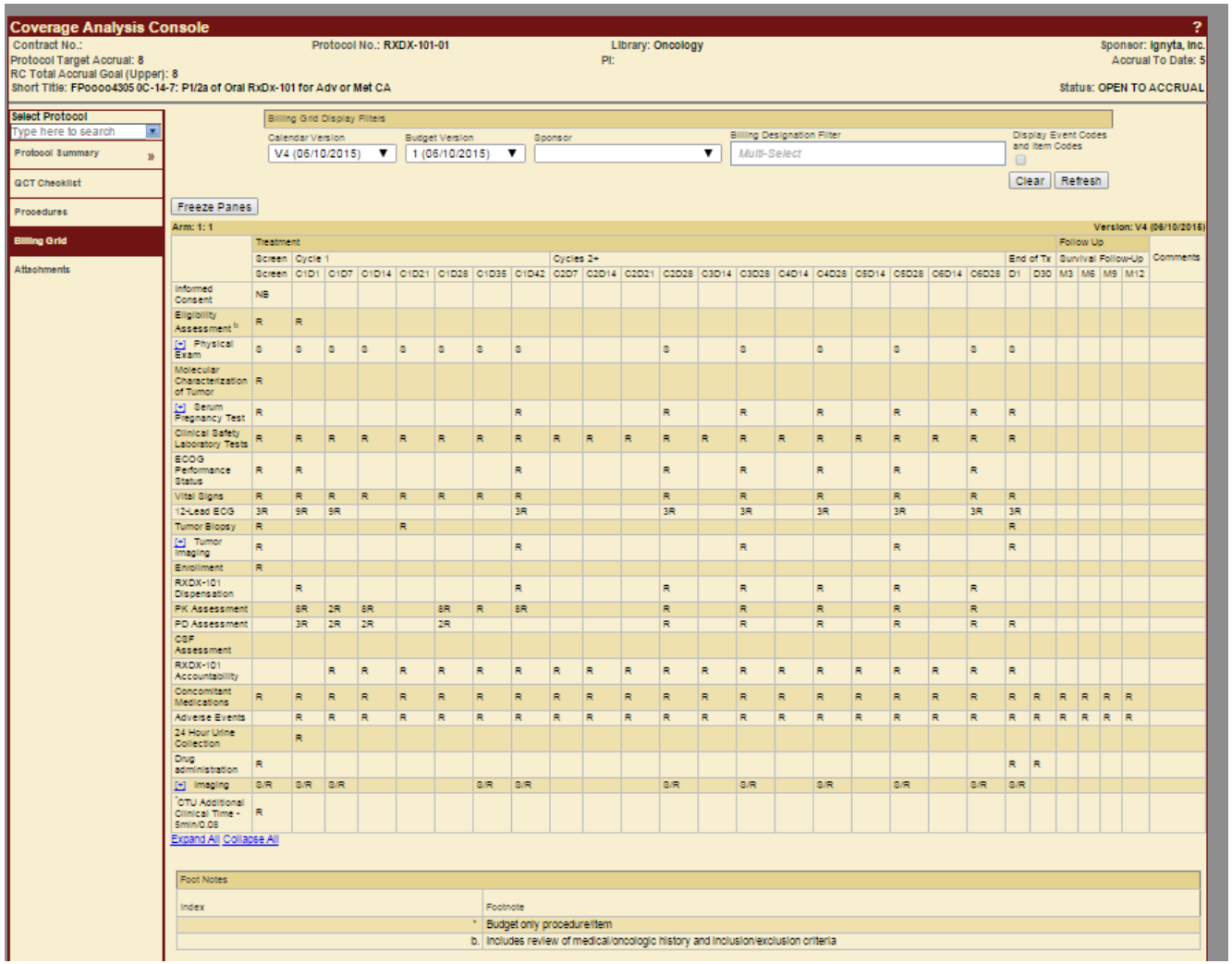
Procedure (Toggle Full Screen)	Forms	Treatment: Screen 1@1Days	Cycle 1: 1 Cycles @42Days							Cycles 2+: 5 Cycles @28Days												End of Tx: 1,30@30Days		Follow Up: Survival Follow-Up			
		Screen	C1D1	C1D7	C1D14	C1D21	C1D28	C1D35	C1D42	C2D7	C2D14	C2D21	C2D28	C3D14	C3D28	C4D14	C4D28	C5D14	C5D28	C6D14	C6D28	D1	D30	M3	M6	M9	M12
Informed Consent		NA																									
Eligibility Assessment[b]		X	X																								
Physical Exam		S	S	S	S	S	S	S	S				S		S		S		S		S	S					
Molecular Characterization of Tumor		X																									
Serum Pregnancy Test		X							X				X		X		X		X		X	X					
Clinical Safety Laboratory Tests		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X					
ECOG Performance Status		X	X						X				X		X		X		X		X						
Vital Signs		X	X	X	X	X	X	X	X				X		X		X		X		X	X					
12-Lead ECG		3X	9X	9X					3X				3X		3X		3X		3X		3X	3X					
Tumor Biopsy		X				X																X					
Tumor Imaging		X							X						X				X			X					
Enrollment		X																									
RXDX-101 Dispensation			X						X				X		X		X		X		X						
PK Assessment			8X	2X	8X		8X	X	8X				X		X		X		X		X						
PD Assessment			3X	2X	2X		2X						X		X		X		X		X	X					
CSF Assessment																											
RXDX-101 Accountability				X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X						
Concomitant Medications		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Adverse Events			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
24 Hour Urine Collection			X																								
Drug administration		X																				X	X				
Imaging		S/X	S/X	S/X				S/X	S/X				S/X		S/X		S/X		S/X		S/X	S/X					

Legend

S = Billable to Patient/Insurance
X = Paid for by Sponsor
NA = Not Billable to Patient/Insurance; Not Paid for by Sponsor

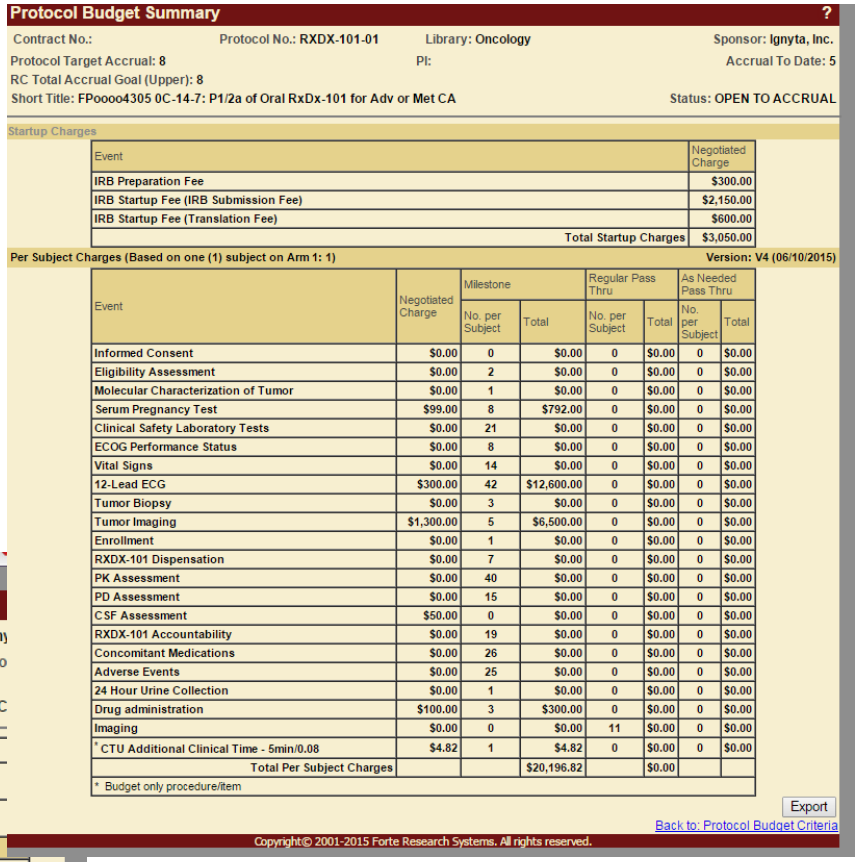
Budget Created From Visits + Fees

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



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)



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Startup Charges

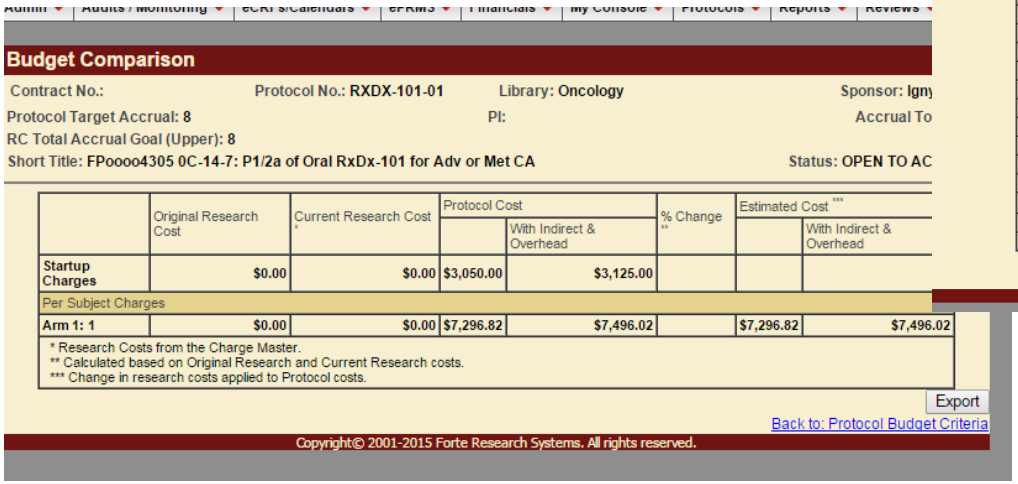
Event	Negotiated Charge
IRB Preparation Fee	$300.00
IRB Startup Fee (IRB Submission Fee)	$2,150.00
IRB Startup Fee (Translation Fee)	$600.00
Total Startup Charges	$3,050.00

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
Total Per Subject Charges			$20,196.82		$0.00		

* Budget only procedure/item

Export
Back to: Protocol Budget Criteria



Budget Comparison

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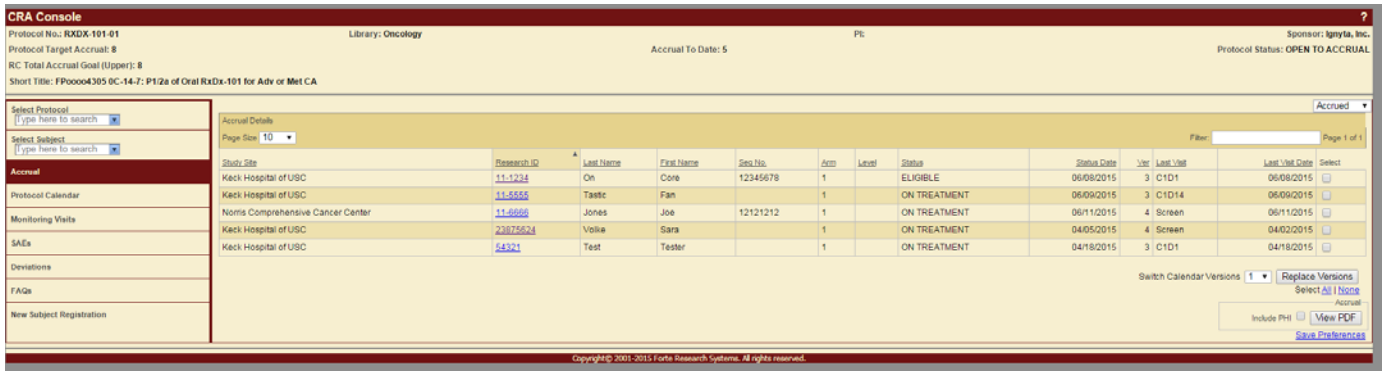
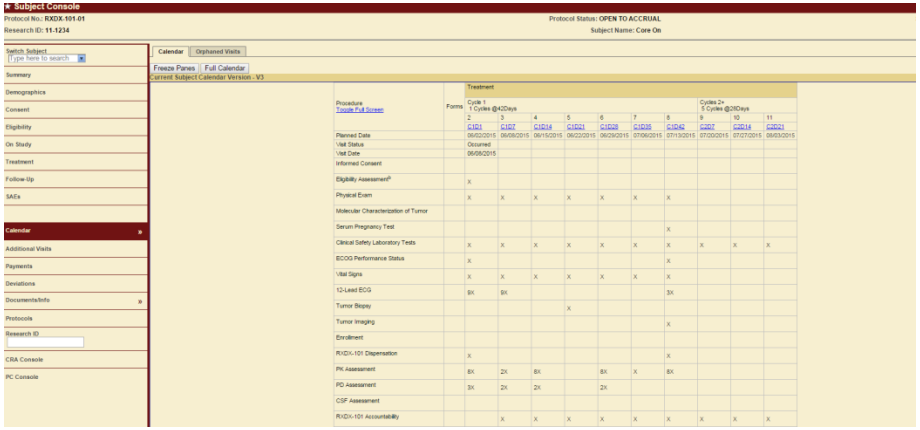
	Original Research Cost	Current Research Cost *	Protocol Cost		% Change **	Estimated Cost ***	
				With Indirect & Overhead			With Indirect & Overhead
Startup Charges	$0.00	$0.00	$3,050.00	$3,125.00			
Per Subject Charges							
Arm 1: 1	$0.00	$0.00	$7,296.82	$7,496.02		$7,296.82	$7,496.02

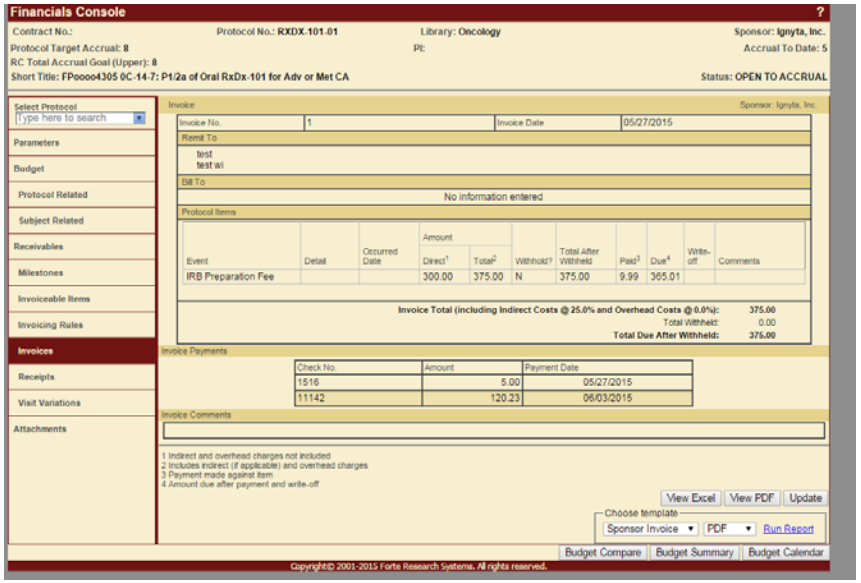
* Research Costs from the Charge Master.
** Calculated based on Original Research and Current Research costs.
*** Change in research costs applied to Protocol costs.

Export
Back to: Protocol Budget Criteria

Subject Tracking & Invoicing







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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

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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

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When will it be ready?

Pilot Go-Live: End of Summer 2015

USC:

End of Summer 2015Go-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 Kuali/KFS and/or CHLA financial systems

(PeopleSoft) biorepository, and registry modules

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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 ☺

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Questions