

Financial Accountability for Clinical Research

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12/11/2025



AGENDA

Clinical Research Budgeting

Medicare Coverage Analysis

Revenue Management

Results



Visit Based Budgeting (VBB)

- VBB is a clinical research budgeting method in which personnel time and effort costs are assigned according to the visits or time points outlined in the protocol.
- Costs for expected time and effort for a particular visit/time point are included via a flat fee rather than by percent effort.
 - Preparing for visit
 - Completing visit
 - Follow up
 - Data entry
 - Regulatory
 - Clinic Support

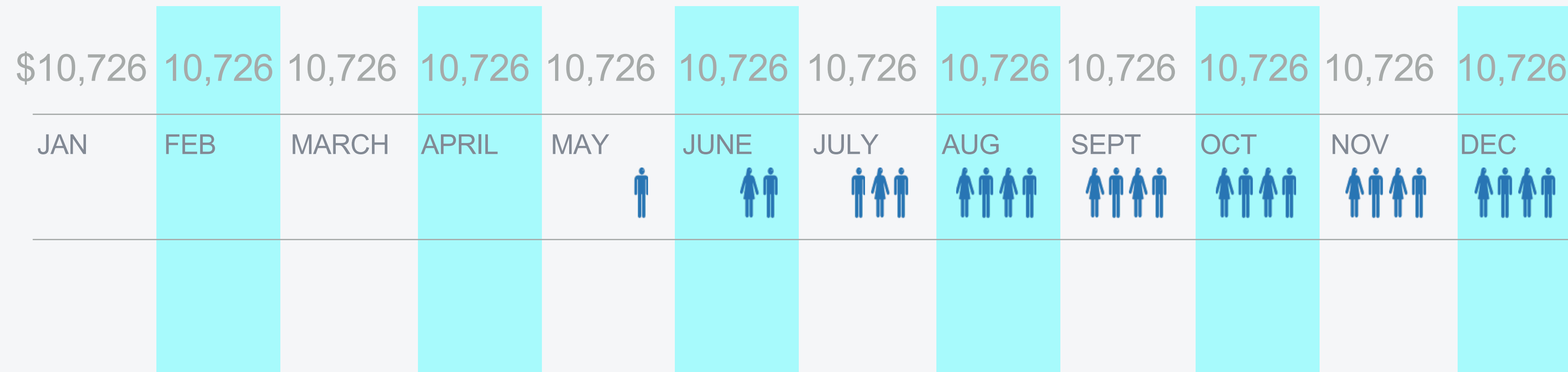


Study Staff Expenses

Therapeutic Trial: Target Accrual: 15 pts/yr • Actual Accrual: 4 pts in year 1

Time and Effort Model

\$128,708

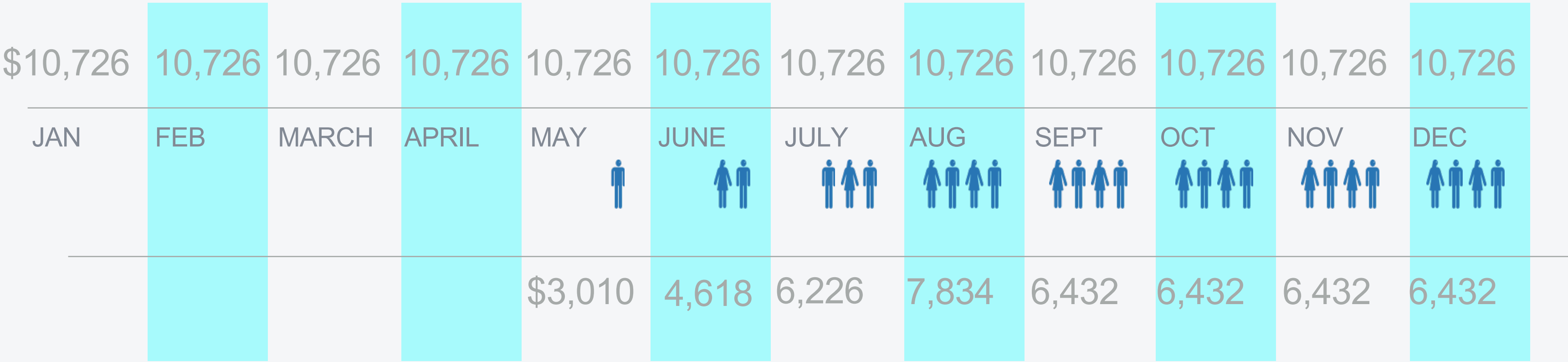


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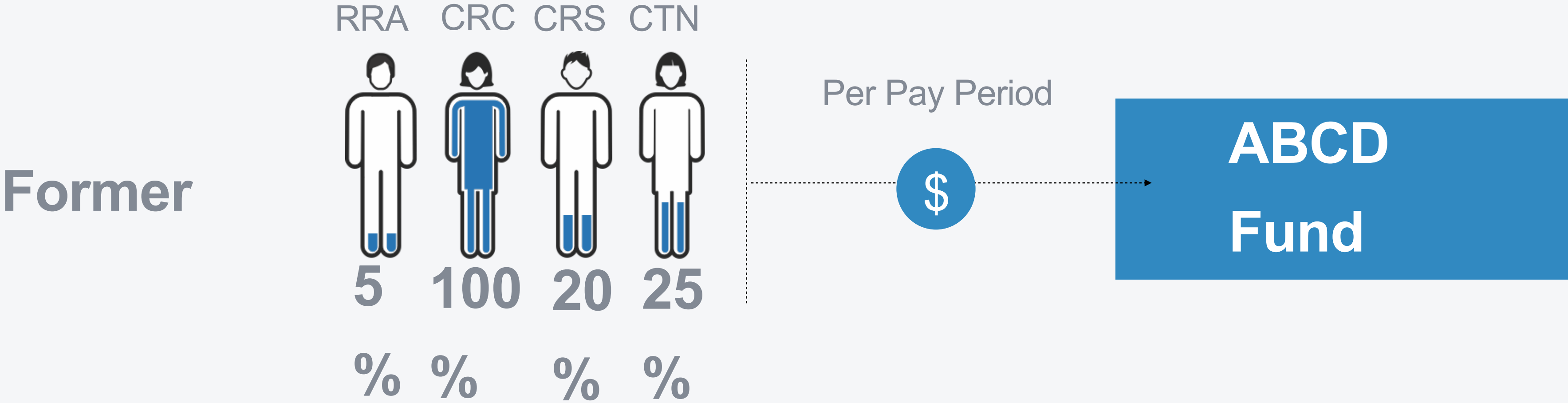
\$128,708



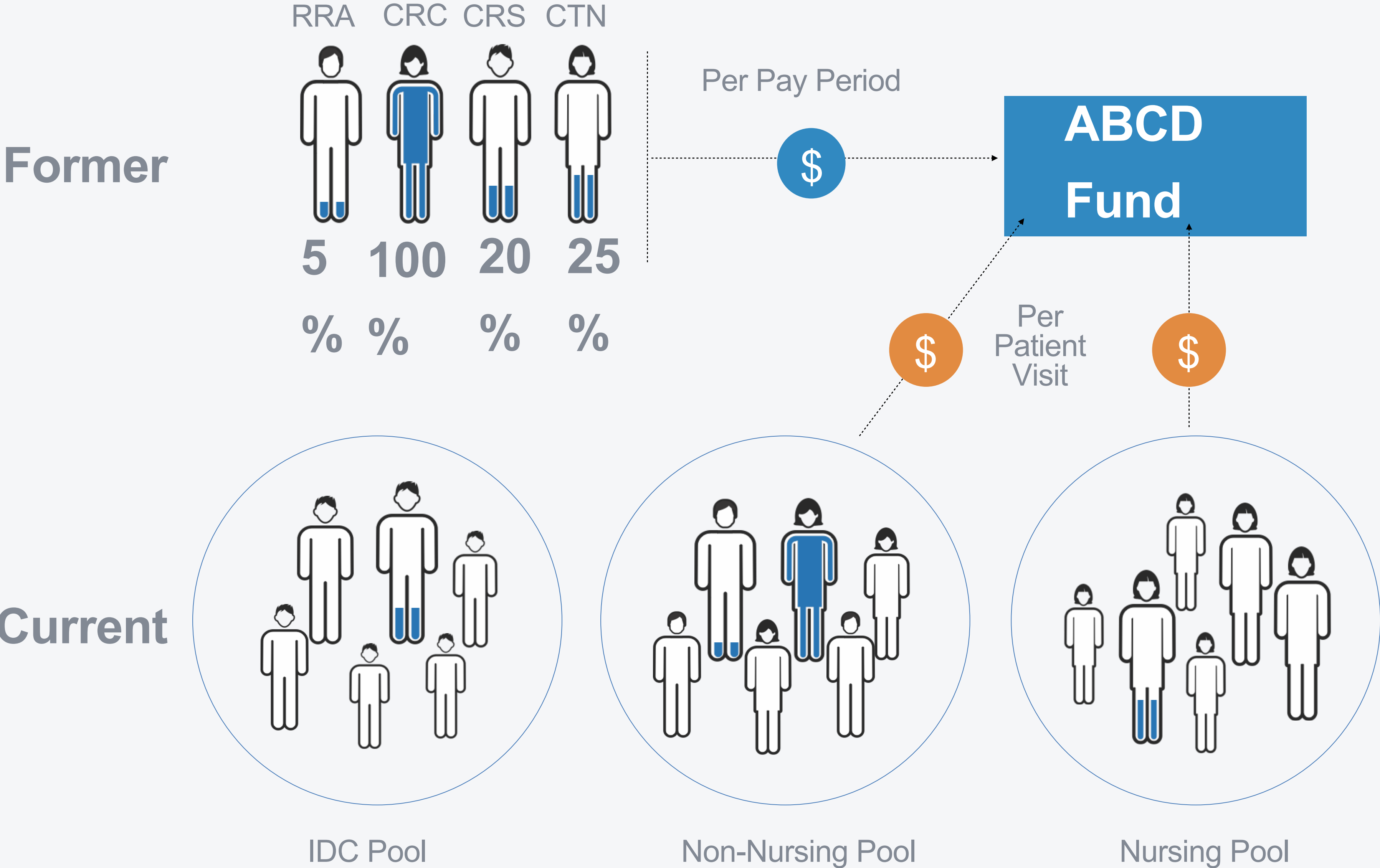
VBB Model - Current

\$47,416

Study Staff Budgeting and Chargeback Changes



Study Staff Budgeting and Chargeback Changes



Visit Based Budgeting

- VBB was implemented across MSK in April 2017
- Simplifies development of internal budget and ensure MSK's costs are covered
- Conforms to industry sponsor requirements
- Aligns with CTMS billing modules to facilitate external billing
- Facilitates internal chargeback/recovery for study staff labor pools



Clinical Trial Budgeting

Clinical trial budgets are comprised of three key components

1. Administrative fees (i.e. IRB review, start-up)
2. Labor costs for Principal Investigator, Non-Nursing Study team, Clinical Trial Nurse
 - Visits within a protocol are assigned a level based on the complexity of the visit (i.e. Screening visits are assigned a high complexity level, follow up visits are assigned a low level of complexity)
3. Research Non-Billable (RNB) fees (i.e. Scans, Blood work)
 - Each procedure, test, and intervention is reviewed to determine if it is billable to the sponsor or to the patient/insurance. Procedures that are deemed as RNB are incorporated into the sponsor budget.



Administrative Fee Schedule

2024 Administrative Fees (INITIAL): All PROTOCOLS (excluding Biospecimen, RRP, Exemptions)			Study Sponsor					
2024 Fee	Frequency Per Protocol	Fee Recovery To:	External For Profit	Internal	Federal	External Not For Profit	Apply IDC Y/N**	Cost Recovery Automation?
Protocol Review and Activation	One Time Fee	CRA/Protocol Review Core (PRC)	\$2,435	\$487	N/A	N/A	N	Y
Clinical Research Administration Activation	One Time Fee	CRA/Protocol Activation Core (PAC)	\$5,500	\$2,500	N/A	N/A	N	Y
Medicare Coverage Analysis (New Protocol)	One Time Fee	CR Finance	\$3,380	\$1,690	N/A	N/A	N	Y
New Protocol Submission (MSK IRB)	One Time Fee	CRA/HRPP	\$3,043	\$2,128	N/A	\$2,128	N	Y
Scientific Review	One Time Fee	CRA/Protocol Review Core (PRC)	\$3,043	\$2,128	N/A	\$2,128	N	Y
Protocol Start-Up Fee	One Time Fee	Respective Labor Pool	\$5,200	N/A	N/A	N/A	N	N
CR Compliance	One Time Fee	CRA/Quality Assurance (QA)	\$1,264	\$1,264	N/A	\$1,264	N	Y
Cross-Filed, Existing IND or IND Exempt Management	One Time Fee	CRA/Reg Oversight & Prod Dev	N/A	\$1,951	N/A	N/A	N	Y
Electronic FDA Submission (eCTD fee) – Full/Cross-filed IND (IND Office)	One Time Fee	CRA/Reg Oversight & Prod Dev	N/A	\$2,424	N/A	N/A	N	N

MSK Internal Budget Example (Personnel)

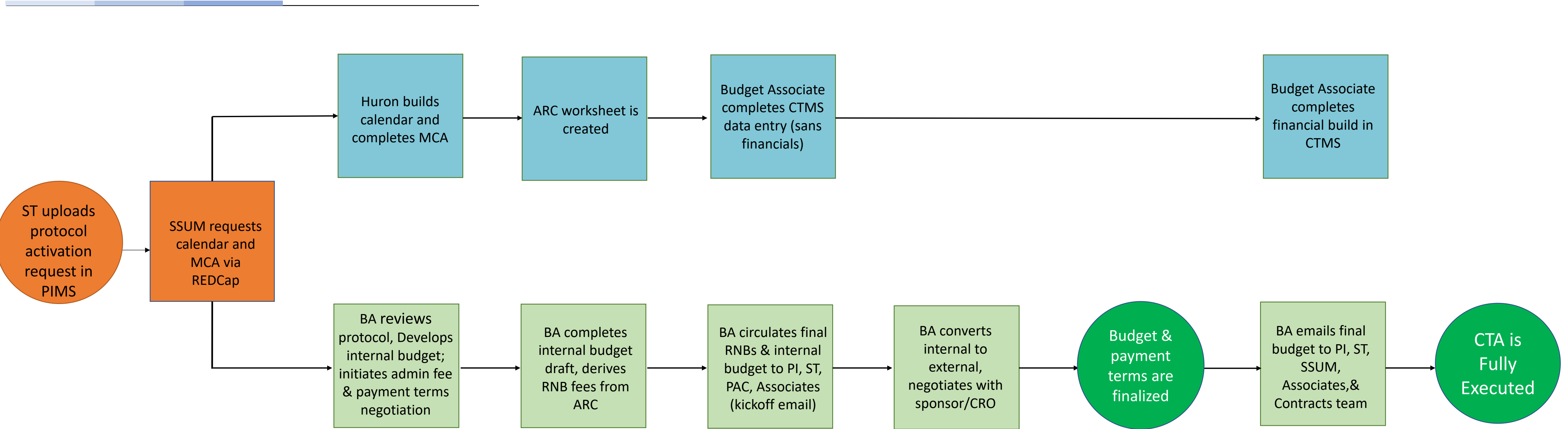
10/30/2023 template version	The Internal Study Budget estimates total expected costs to be incurred at MSKCC. Please note, costs in this budget may be more or less than what is negotiated in an external contract or grant with a non-MSK funding source.												
Project Title:	Phase X Interventional/Therapeutic Protocol												
Principal Investigator:	Dr. Smith					Protocol Sponsor/Author Type	External For-Profit						
Protocol ID:	MED23-XXX					Funding Source:	External For-Profit						
						Type of Study:	Therapeutic						
Total Expected Accrual:	10					Name of Sponsor:	Industry						
Expected Subjects/Year:	5					Name of CRO:							
Expected time to accrue:	2												
Expected time on treatment:	12 months												
Expected time in follow-up:	5Y					NOTES:							
Principal Investigator Percent Time and Effort	5%				update if waived								
# of external Multicenter sites (Non-Alliance, Non-CHERP):	0												
Overhead (IDC) Percentage (update if not 35%)	35%												
RFM Look Up													
Markup	20%												
VISIT-BASED FEES	Screening	C1D1	C1D15	C2D1	C3D1	C4D1	C5+D1	EOT	STFU @ 30 Days	LTFU (q3M for 5Y)	Total per patient/All Occurrences	Total for All patients/ Occurrences	
Visit Complexity	LP 7	LP 7	LP 5	LP 6	LP 6	LP 6	LP 6	LP 7	LP 4	LP 1			
Anticipated # of occurrences/subject	1	1	1	1	1	1	7	1	1	20			
Personnel (Therapeutic Chargebacks)													
Principal Investigator	\$916	\$916	\$558	\$677	\$677	\$677	\$677	\$916	\$381	\$34	\$11,137	\$111,370.00	
Non-Nursing Study Staff	\$916	\$916	\$558	\$677	\$677	\$677	\$677	\$916	\$381	\$34	\$11,137	\$111,370.00	
Nursing Study Staff	\$586	\$586	\$371	\$494	\$494	\$494	\$494	\$586	\$186	\$31	\$7,871	\$78,705.00	
Nursing Study Staff (INPATIENT NURSE)											\$0	\$0.00	
SUBTOTAL PERSONNEL (DC only)	\$2,418.30	\$2,418.30	\$1,486.70	\$1,847.90	\$1,847.90	\$1,847.90	\$1,847.90	\$2,418.30	\$947.90	\$98.80			
20%	\$2,901.96	\$2,901.96	\$1,784.04	\$2,217.48	\$2,217.48	\$2,217.48	\$2,217.48	\$2,901.96	\$1,137.48	\$118.56			

MSK Internal Budget Example (Research Sample Collection, SOC & RNB Elements)

	Screening	C1D1	C1D15	C2D1	C3D1	C4D1	C5+D1	EOT	STFU @ 30	LTFU (q3M for	Total per patient	Total for All
Research Sample Collections												
DTU Industry rates												
DTU Level	Select	Inpatient	Simple	Complex	Simple	Simple	Simple	Moderate	Select	Select		
DTU Price		\$2,400	\$180	\$1,200	\$180	\$180	\$180	\$500			\$5,900	\$59,000.00
CSP Price List												
Correlative Sciences Program - Blood Samples Level 1: 1 Sample Level 2: 2-5 Samples Level 5 = 6+ Samples	[Select CSP Level]	Level 5	Level 1	Level 5	Level 1	Level 1	Level 1	Level 5	[Select CSP Level]	[Select CSP Level]		
CSP Price		\$250.00	\$80.00	\$250.00	\$80.00	\$80.00	\$80.00	\$250.00			\$1,550	\$15,500.00
Correlative Sciences Program - Tissue Samples Level 3: Archival Tissue Level 4: Fresh Biopsy	Level 4	[Select CSP Level]	[Select CSP Level]	[Select CSP Level]	[Select CSP Level]	[Select CSP Level]	[Select CSP Level]	Level 4	[Select CSP Level]	[Select CSP Level]		
CSP Price	\$190.00							\$190.00			\$380	\$3,800.00
Venipuncture/Port Draw (if research bloods drawn on days routine bloods are not collected)											\$0	\$0.00
Fresh Tumor Biopsy	X							X			\$0	\$0.00
PKs		6X	X	6X	X	X	X	6X			\$0	\$0.00
ADA		X		X				X			\$0	\$0.00
[Insert other RNBs]											\$0	\$0.00
SUBTOTAL RNBs (IDC to be applied, when applicable)	\$190.00	\$2,650.00	\$260.00	\$1,450.00	\$260.00	\$260.00	\$260.00	\$940.00	\$0.00	\$0.00		
	Screening	C1D1	C1D15	C2D1	C3D1	C4D1	C5+D1	EOT	Days	5Y)	Total per patient	patients/Occur
Procedures												
Dispensing Fee		\$92.00		\$92.00	\$92.00	\$92.00	\$92.00				\$1,012	\$10,120.00
Triplicate ECG		N/A - Sponsor		N/A - Sponsor				N/A - Sponsor			\$0	\$0.00
Physical Exam	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC		\$0	\$0.00
Pregnancy Test	SOC	SOC		SOC	SOC	SOC	SOC	SOC			\$0	\$0.00
Hematology	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC		\$0	\$0.00
Chemistry	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC		\$0	\$0.00
Chemistry - GGT	\$98.15	\$98.15	\$98.15	\$98.15	\$98.15	\$98.15	\$98.15	\$98.15	\$98.15		\$1,472	\$14,722.50
Chemistry - Uric Acid	\$72.80	\$72.80	\$72.80	\$72.80	\$72.80	\$72.80	\$72.80	\$72.80	\$72.80		\$1,092	\$10,920.00
SUBTOTAL Correlatives (IDC to be applied)	\$170.95	\$262.95	\$170.95	\$262.95	\$262.95	\$262.95	\$262.95	\$170.95	\$170.95	\$0.00		
Sub-Total	\$3,262.91	\$5,814.91	\$2,214.99	\$3,930.43	\$2,740.43	\$2,740.43	\$2,740.43	\$4,012.91	\$1,308.43	\$118.56	\$28,884.43	
IDC/Overhead 35%	\$1,142.02	\$2,035.22	\$775.25	\$1,375.65	\$959.15	\$959.15	\$959.15	\$1,404.52	\$457.95	\$41.50	\$10,109.55	
Total with Overhead	\$4,404.93	\$7,850.13	\$2,990.24	\$5,306.08	\$3,699.58	\$3,699.58	\$3,699.58	\$5,417.43	\$1,766.38	\$160.06	\$38,993.98	
TOTAL based on # of occurrences	\$4,404.93	\$7,850.13	\$2,990.24	\$5,306.08	\$3,699.58	\$3,699.58	\$25,897.06	\$5,417.43	\$1,766.38	\$3,201.12	\$64,232.53	\$642,325.28

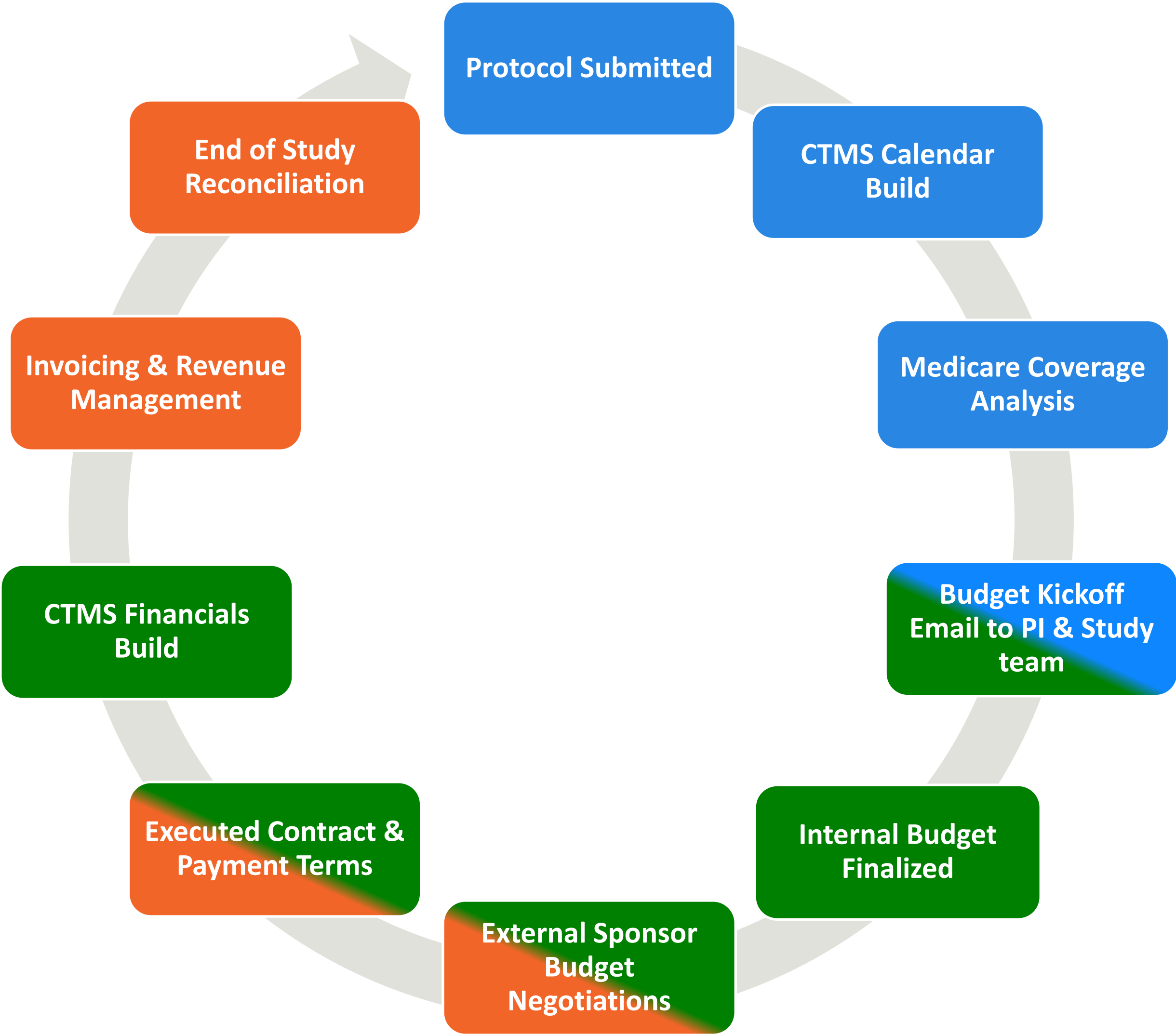
CR Finance Budget Development Workflow

Industry-sponsored therapeutic, therapeutic/QoL and diagnostic clinical trials



- Key:**
- ARC: Application for Research Charges
 - BA: Budget Analyst
 - CTA: Clinical Trial Agreement
 - CTMS: Clinical Trial Management System
 - IRB: Institutional Review Board
 - MCA: Medicare Coverage Analysis
 - PI: Principal Investigator
 - PIMS: Protocol Information Management System
 - SSUM: Senior Start Up Manager
 - ST: Study Team

CR Finance workflow Responsibilities within Protocol Lifecycle



Medicare Coverage Analysis (MCA)

- An MCA is required for all clinical trials in which tests, procedures, and interventions associated with a clinical trial are invoiced to third party payers.
- Preparing an MCA involves determining the underlying eligibility of the study for Medicare coverage and reviewing clinical events specified in the protocol to determine which can be reimbursed by Medicare.
- MCA is a centralized process within the CR Finance unit.



Medicare Coverage Analysis

- Research non-billable and standard of care billing designations and are entered directly into the Clinical Trial Management System (CTMS) billing grid.
- A justification, National Coverage Determination or Local Coverage Determination is recorded in the CTMS.
- CR Finance provides investigators the completed MCA.



Medicare Coverage Analysis

- MCA is performed by certified Coverage Analysts (Huron- LLC).
- MSK accepts Huron's designations.
- Investigators can request updates to designations at the service level.
- Service level designation updates require approval from the Service Chief and CRA Leadership.
- Designation updates are added to MSK or service specific standard of care lists.



Medicare Coverage Analysis Example

Arm ESC: ESC: Dose Escalation Cohort (Phase 1)	Protocol No.: MED20-xxx												Version: V1 (Coverage Analysis Signoff) A0	
	Treatment													
	Screening 1@28Days	TREATMENT CYCLES For ESCALATION COHORT 35 Cycles @21Days												
	Day -28 to -1	C1D1	C1D2	C1D3	C1D4	C1D8	C1D15	C2D1	C3D1	C4D1	C5D1	C6D1	Comments	
Visit Site	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA		
DTU Level 1			RNB(TE)	RNB(TE)	RNB(TE)	RNB(TE)	RNB(TE)							
DTU Level 2								RNB(TE)	RNB(TE)	RNB(TE)	RNB(TE)	RNB(TE)		
Complete Physical Exam ⁷	Pt1(CC)	RNB							RNB		RNB			
													This item may include the following CPT codes: 99201-99215, G0463	
													Per NCCN Guidelines Version 3.2020 Non-Small Cell Lung Cancer a physical exam is recommended at work-up and every 3-6 months for the first 3 years and then every 6 months for the next 2 years during follow-up	
													Coverage is supported for this patient population at screening under NCD 310.1	
													A conventional care reference could not be found to support a physical exam during treatment in this patient population. In addition, as this is a first in human trial, no side effects of the study drug warrant a physical exam during treatment. It should therefore be considered research-related and paid for by the sponsor when performed during treatment.	
Venipuncture	Pt1(SM)	Pt1(SM)	RNB	RNB	RNB	Pt1(SM)	RNB	Pt1(SM)	Pt1(SM)	Pt1(SM)	Pt1(SM)	Pt1(SM)	This item may include the following CPT codes: 36415, 36591, 36592	
													Venipuncture is a medically necessary component of laboratory blood testing. To the extent that the laboratory blood tests are covered as part of this analysis, so too is the venipuncture.	
													Coverage is supported for this patient population at screening, day 1 throughout treatment, cycle 1 day 8, and during follow-up under NCD 310.1	
													A conventional care reference could not be found to support performing a venipuncture in this patient population at Cycle 1 Days 2, 3, 4, and 15. It should therefore be considered research-related and paid for by the sponsor when performed at these time points	

RNB – Research non-billable

Pt1 – Billable to patient

NA – Not Applicable/Billable

CC – Conventional Care

T&E – Time and Effort

SM – Safety Monitoring

Medicare Coverage Analysis (MCA)

- MSK global standard of care list.
- Procedures are deemed as billable by MSK to patient’s insurance.
- List streamlines MCA and expedites budget development & negotiation.

TEST / PROCEDURE	CPT CODE
AMYLASE BLOOD	82150
AUTOMATED URINALYSIS W/ MICRO	81001
CBC W/ AUTOMATED DIFFERENTIAL	85025
COMPREHENSIVE METABOLIC PANEL	80053
CREATINE PHOSPHOKINASE	82550
D DIMER	85379
DIRECT BILIRUBIN	82248
ECG, SINGLE	93000-9310
ECHO (SCREENING)	93306
FIBRINOGEN	85385
FOLLICLE STIMULATING HORMONE	83001
*FREE T3, BLOOD	84481
*FREE T4	84439
HCG QUALITATIVE SERUM	84703
HCG QUALITATIVE URINE	84703
HEPATITIS B SURFACE ANTIBODY	86706
HEPATITIS BC ANTIBODY	86704
HEPATITIS BS ANTIGEN	87340
HEPATITIS B PCR	87517
HEPATITIS C ANTIBODY	86803
HEPATITIS C PCR, QUANTITATIVE	87522
HIV AG/AB	87389
HIV PCR	87536
LACTIC DEHYDROGENASE	83615
LIPASE SERUM	83690
MAGNESIUM BLOOD	83735
MUGA (SCREENING)	78472
±OPHTHALMOLOGY EXAMS	US0001, US0017
PARTIAL THROMBOPLASTIN TIME	85730
PHOSPHORUS SERUM	84100
PHYSICAL EXAMS	Evaluation and Management code will be applied as appropriate
PROTHROMBIN TIME	85610
SCANS (SCREENING – PT(INV))	Scan code(s) will be applied as appropriate
*THYROID STIMULATING HORMONE	84443

±Drug class of MEK Inhibitors
*Tests will be considered billable for drug classes: tyrosine kinase inhibitors and immunotherapeutic

Revenue Management

- The Revenue Management team within CR Finance is responsible for:
 - Submitting invoices to sponsors for activity recorded in the CTMS including administrative fees, visits, milestones, and RNBs
 - Identifying and applying payments made by sponsors
 - Performing end of study reconciliations
 - Financial build review within the CTMS



The Clinical Trials Management System (CTMS) is software designed to capture the patient and financial data of clinical trials.

CRA Console

Protocol No.: 18-002

Protocol Target Accrual: 30

RC Total Accrual Goal (Upper): 0

Short Title: TRAINING: CRSp Registration

Library: Oncology

Accrual To Date: 12

PI: Khan, Atif

Sponsor: Clovis Oncology

Protocol Status: OPEN TO ACCRUAL

Select Protocol

18-002

Select Subject

Accrual

Protocol Calendar

Monitoring Visits

Financial Events

SAEs

Deviations

FAQs

Accrual Details

Page Size 10

Filter:

<<< < > >>>

Page 1 of 2

Study Site	MRN	Last Name	First Name	Seq No.	Arm	Level	Status	Status Date	Ver	Last Visit	Last Visit Date	Select
MSK - Manhattan	5547	Metzker	Nicholina	15	1	1	ON TREATMENT	07/15/2018	1	-30 to 0 Days	07/01/2018	<input type="checkbox"/>
MSK - Manhattan	MSK3612	Vader	Darth	8	1	3	ON TREATMENT	07/15/2018	1	Week 2	08/20/2019	<input type="checkbox"/>
MSK - Manhattan	MSK3625	Flintsone	Wilma	9	1	-1	ON TREATMENT	10/03/2018	1	Week 1	10/03/2018	<input type="checkbox"/>
MSK - Bergen	MSK6488	shoulders	elan	10	1	0	ON TREATMENT	10/03/2018	1			<input type="checkbox"/>
MSK - Manhattan	MSK6489	Di Rienzo	Jacki	12	1	1	ON TREATMENT	07/15/2018	1	-30 to 0 Days	07/01/2018	<input type="checkbox"/>
MSK - Manhattan	MSK6490	Espeleta	James	13	1	1	ON TREATMENT	07/15/2018	1	-30 to 0 Days	07/01/2018	<input type="checkbox"/>
MSK - Manhattan	MSK6491	Samson	Cheyenne	14	1	1	ON TREATMENT	07/15/2018	1	-30 to 0 Days	07/01/2018	<input type="checkbox"/>
MSK - Manhattan	MSK6492	Lopez	Melissa	11	1	1	ON TREATMENT	07/15/2018	1	-30 to 0 Days	07/01/2018	<input type="checkbox"/>
MSK - Manhattan	MSK6493	Belizaire	Kendra	16	1	1	ON TREATMENT	07/15/2018	1	-30 to 0 Days	07/01/2018	<input type="checkbox"/>
MSK - Commack	MSK6494	Chip	Potato	17	1	0	ON TREATMENT	10/03/2018	1			<input type="checkbox"/>

Switch Calendar Versions 1 (A(0))

Replace Versions

Select All | None

Accrual

Include PHI ☐

View PDF

Save Preferences

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Example of patients tracked in CTMS

Patient calendars are built to record patient visits and procedures completed.

[illegible]

Each visit timepoint has a pre-populated list of procedures to be checked out by study teams.

Subject Visit Update

User: Kevin Frodell

Protocol No.: 18-002

Protocol Status: OPEN TO ACCRUAL

Subject Status: ON TREATMENT

MRN: MSK3612

Subject Name: Darth Vader

Sequence No.: 8

Visit Details

Phase: Treatment Visit: Week 2 Version: V1 (05/14/2018)

Visit Date08/20/2019

Visit StatusAcknowledged

Visit Tolerance+/-0

Visit Description

Reset Calendar?All Visits

Data Collection Completed

Monitored

Submitted

Locked

Date

Date

Date

Date

Clinical Comments

Data Comments

Procedures

Procedure	Procedure Date	SOC	SOC Modifier	Missed	Missed Count	N/A
Visit Site	07/23/2018	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
MSK Bergen						
Physical examination	07/23/2018	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
Adverse event monitoring	07/23/2018	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
Drug diary review	07/23/2018	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
Rucaparib ^a	07/23/2018	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
Radiation Therapy	07/23/2018	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>

Foot Notes

a Rucaparib will be administered concurrently with RT, commencing with fraction #1 and daily throughout RT

Close

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The system cross-references this data entry with financial parameters built into each calendar, creating a list of invoiceable visits and procedures.

Subject Milestone Items

[More Detail](#)

Show 10 entries

Filter

Sequence No.	Initials	Milestone	Occurred Date	Direct	Total	Withhold	Total After Withheld	Select	NA
No data available in table									

Showing 0 to 0 of 0 entries

Previous Next

Pass Thru Items

[More Detail](#)

Show 10 entries

Filter

Procedure/Lab	Sequence No.	Initials	Milestone	Occurred Date	Direct	Total	Withhold	Total After Withheld	Select	NA
Pass	2	BT	Baseline	10/25/2018	2,771.55	2,771.55	<input type="checkbox"/>	2,771.55	<input type="checkbox"/>	<input type="checkbox"/>
Pass	22	BT	Baseline	10/25/2018	2,771.55	2,771.55	<input type="checkbox"/>	2,771.55	<input type="checkbox"/>	<input type="checkbox"/>
Pass	3	BT	Baseline	10/25/2018	2,771.55	2,771.55	<input type="checkbox"/>	2,771.55	<input type="checkbox"/>	<input type="checkbox"/>
Pass	4	BT	Baseline	10/25/2018	2,771.55	2,771.55	<input type="checkbox"/>	2,771.55	<input type="checkbox"/>	<input type="checkbox"/>
Pass	26	BT	Baseline	10/25/2018	2,771.55	2,771.55	<input type="checkbox"/>	2,771.55	<input type="checkbox"/>	<input type="checkbox"/>
Pass	25	BT	Baseline	10/25/2018	2,771.55	2,771.55	<input type="checkbox"/>	2,771.55	<input type="checkbox"/>	<input type="checkbox"/>
Pass	24	BT	Baseline	10/25/2018	2,771.55	2,771.55	<input type="checkbox"/>	2,771.55	<input type="checkbox"/>	<input type="checkbox"/>
Pass	23	BT	Baseline	10/25/2018	2,771.55	2,771.55	<input type="checkbox"/>	2,771.55	<input type="checkbox"/>	<input type="checkbox"/>
Pass	21	BT	Baseline	10/25/2018	2,771.55	2,771.55	<input type="checkbox"/>	2,771.55	<input type="checkbox"/>	<input type="checkbox"/>
Pass	18	BT	Baseline	10/25/2018	2,771.55	2,771.55	<input type="checkbox"/>	2,771.55	<input type="checkbox"/>	<input type="checkbox"/>

Showing 1 to 10 of 24 entries

Previous 1 2 3 Next

The Revenue Management team is easily able to create invoices within the system and send to the sponsor for payment.

Invoice

Sponsor: Calithera Biosciences

Invoice No.	1001012	Other Invoice No.		Invoice Date								
Bill To												
No information entered												
Pass Thru Items												
Procedure/Lab	Sequence No.	Initials	Visit	Occurred Date	Amount							
					Direct ¹	Total ²	Withhold?	Total After Withheld	Paid ³	Due ⁴	Write-off	Comments
Pass	2	BT	Baseline	10/25/2018	2,771.55	2,771.55	N	2,771.55		2,771.55		
Invoice Total (including Indirect Costs @ 0.0% and Overhead Costs @ 0.0%):										2,771.55		
Total Withheld:										0.00		
Total Due After Withheld:										2,771.55		

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 Summary

Budget Calendar

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Financial Management of Clinical Trial Funds

- Revenue Management partners with Research Financial Management, Budget & Billing Compliance, and Protocol Operations to monitor research fund balances and review fund deficits
 - Quarterly fiscal management meetings are held at the department level to review funds in deficit and identify causes and solutions
 - Monthly deficit escalation meetings are held to review the largest fund deficits and ensure progress is being made towards deficit resolution
 - Reducing deficits is a shared institutional goal between Revenue Management, Research Financial Management, and Budget & Billing Compliance

Research Charge Analysis

What We Do

- Review and route charges for research patients in Epic

Quick Facts

- We review 100% of charges for research patients
- We review both hospital billing and physician billing
- We sometimes review 10M worth of charges in a single day



Study
Related-Bill to
Insurance/
Patient (SOC)



Study
Related-Bill
to Study
(RNB)



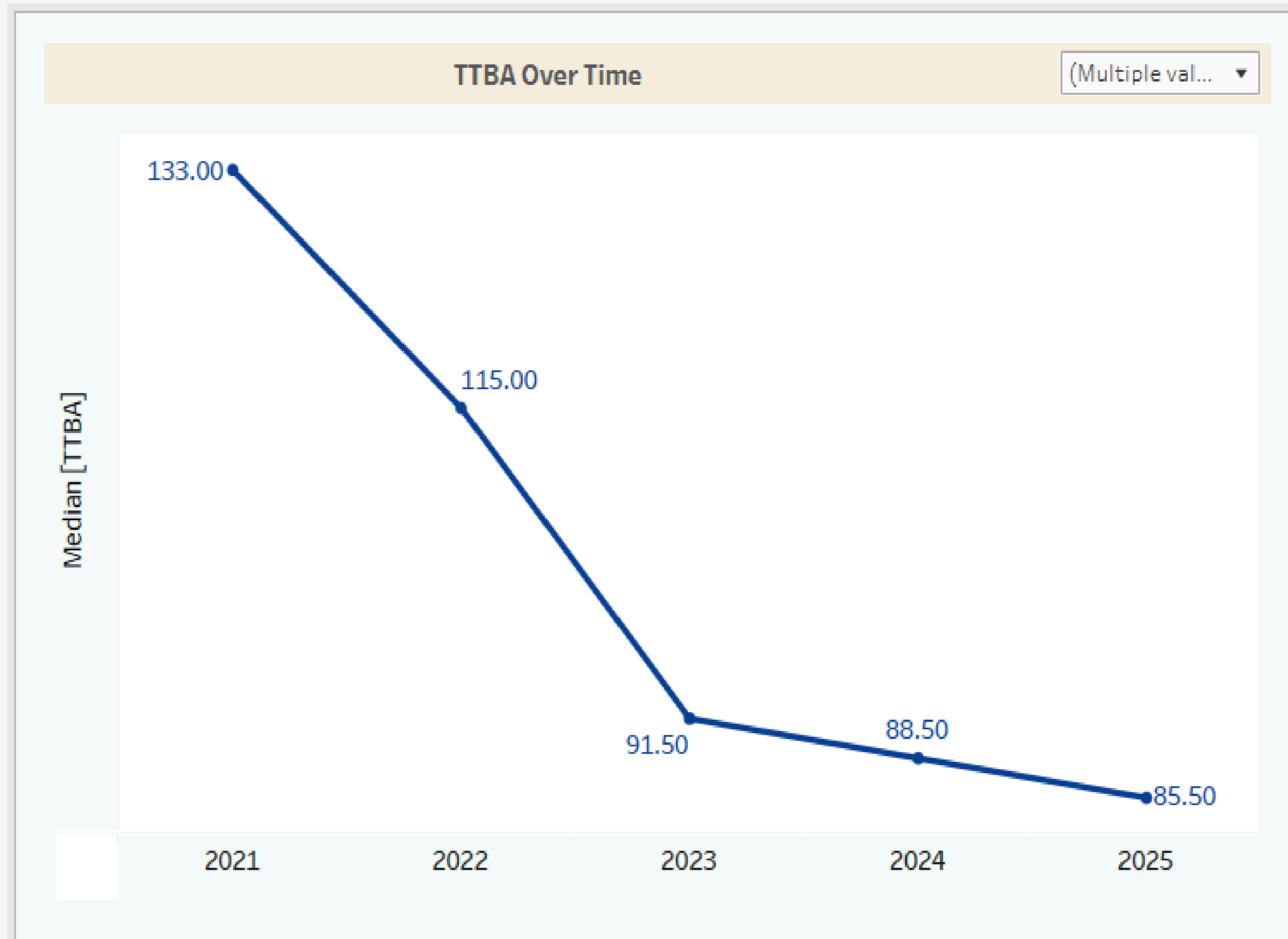
Non-
Study
Charges

Results and team accomplishments (2020 – 2025)

- Completed centralization of Medicare coverage analysis, budget development and negotiation, and revenue management
- Established MSK and service specific MCA lists, created two-year rate cards, developed negotiation tactics playbook and payment terms guidelines
- Implemented Epic for CR Finance procedures including establishment of Research Charge Analysis team
- Partnered with CR IT, RTM IT and IO to adopt technological solutions to optimize CR Finance and CRA processes including
 - CR Finance workload analysis dashboards
 - Chargeback automations for Labor Pools and CRA Fees
 - CTMS to ARC integration for new and amended studies
 - RM activity triggers (i.e. invoiceable items)
 - Epic implementation
 - LOI intake
- Achieved revenue records year over year for 8 consecutive years (sans 2020) averaging 15%+ increases. On pace for \$175M+ in revenue in 2025.
- Accounts receivable, aging invoices and unapplied payments in 2025 are at lowest amount since tracking these KPIs

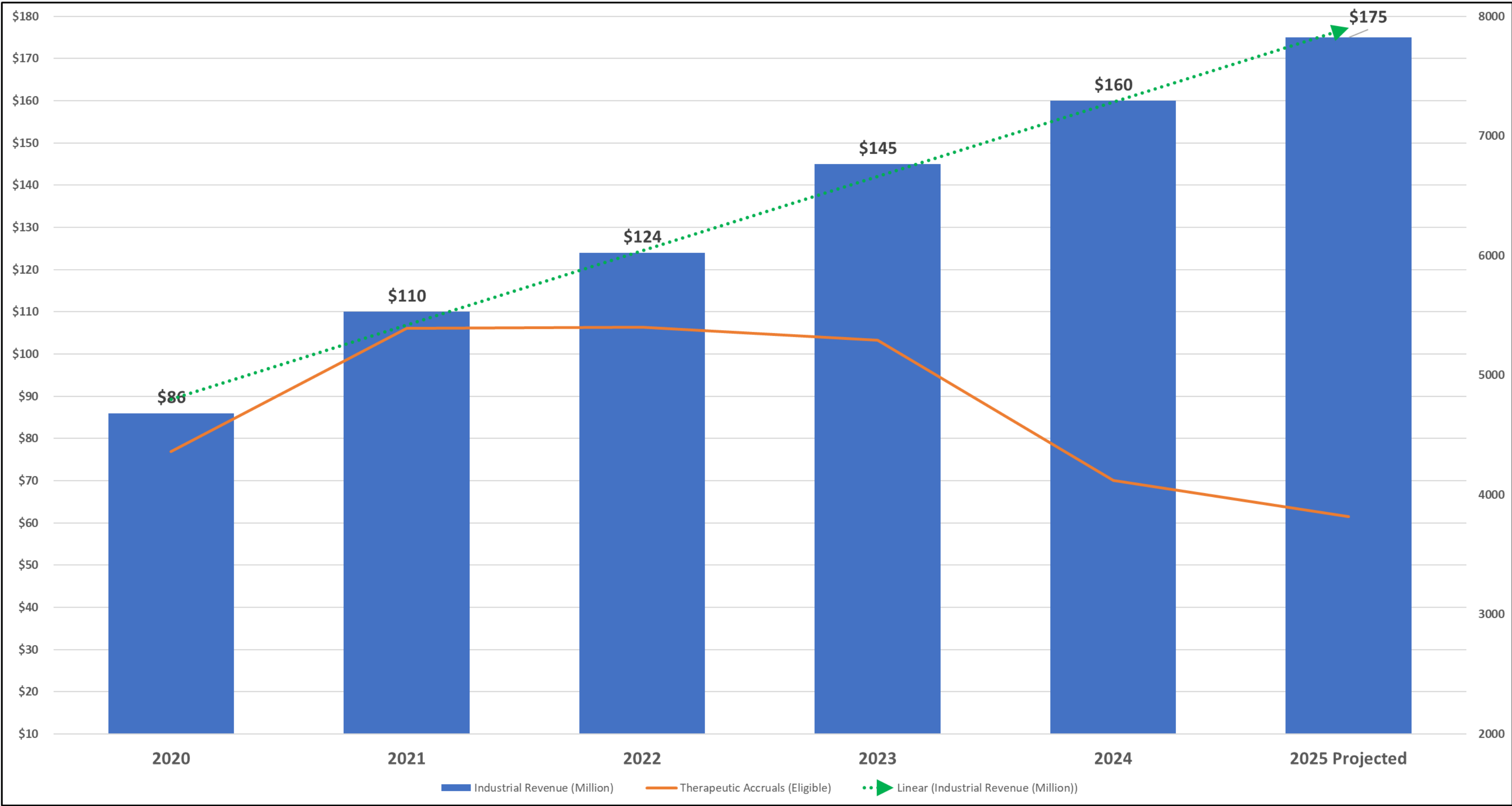


Results and team accomplishments (2018 – 2025)



- Overall CTA TTBA: 85.5 days (lowest on record)
- Priority 1 study TTBA: 53 days (lowest on record)
- Accelerated Advantage TTBA: 16 days (world-class)
- Median TTBA down ~30 days since 2022; on pace for fastest year
- Drivers: process enhancements, automation, and efficiency.

RESULTS: Revenue



Figures projected for 2025

Thank you!

