

Using Feasibility to Select the Best Studies for your Organization

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Services Available from OCR

- [OnCore](#)
- [Participant Payments](#)
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OCR Feasibility Assessment Services

The free [OCR feasibility process](#) can be requested by anyone!

There are a series of assessments, starting with the simplest and moving to the most complex

1. GO/NO GO checklist - *if the response is GO then move to*
2. Weighted Risk Assessment - *if there is a favorable score then move to, if determined to be needed*
3. Break-even Analysis - *studies that need a deeper dive and clearer financial projections and information*



Weighted Feasibility Risk Assessment

Under	Reference	Low (1 point)	Medium (2)	High (3)	1
Yes/no	More than 10 y 5-10 years less than 5 years	Sponsor info (c.) Previous experiences with CRO/Sponsor (investigator side)			
More than 10 y 5-10 years less than 5 years	Sponsor info (c.) Previous experiences with CRO/Sponsor (CRO Side) Yes/No				
Phase	IV - Postmarket	II/III	Pilot or I	Drug or device (j)	
NA	No	Drug or device (i) FDA Approved/CMS Approval/ Category B letter from FDA			Yes
(j) Competing trials? (Yes/No)	No	NA	Yes	Competing trials	
Prior enrollment history	Yes	NA	No	Enrollment (k)	
Potential Population through TriNetX	More than 100 10-100 less than 10	Patient info (l) Number of patients with study indication			
TriNetX, p-Patient info (l)	Source of patients (i.e., TriNetX, clinic, referral, pre-admission, testing, in Clinic, inpatient, Outpatient, te Referral,				
Low criteria	Midde of the	Higher # of criteria: Patient info (l)		Exclusion criteria	
Lowish burden	Moderate bur	Yonr burdannon		Patient info (l) Potential burden to or biog	
More than 10 y 3-10 years less than 3 years	Principal Investigator Prior experiences				
Very available	Judging a few	Not very available		PI Availability Principle Investigator	
More than 10 y 3-10 years less than 3 years	Sponsor info (c.) Cases Sub Investigator Sub sponsor				
Very available	Judging a few	Not very available		Coordinating Staff Avail Coordinating staff	
Yes	Mod	Coordinating staff, coordinating staff			

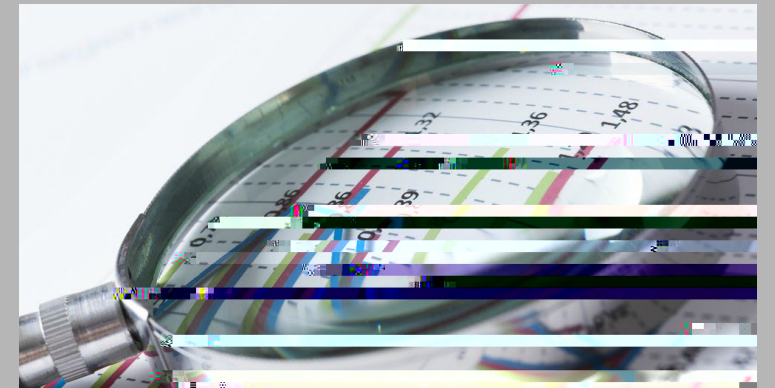
Break-even Analysis

The Break-even Analysis Feasibility tool consists of three domains:

(1) Protocol Related

(2) Financial

(3) Department Specific



Break-even Analysis

Results:

Break-even Point (Units): 1

Sales volume analysis:

	60,410.10	60,410.10	60,410.10	60,410.10	60,410.10	60,410.10	60,410.10	60,410.10	60,410.10	60,410.10	60,410.10	60,410.10
Subject Per Visit	73,704.44	73,704.44	73,704.44	73,704.44	73,704.44	73,704.44	73,704.44	73,704.44	73,704.44	73,704.44	73,704.44	73,704.44
Fixed costs per period	0.00	430.00	601.00	1,220.00	1,720.00	2,104.00	2,304.00	3,010.00	3,440.00	3,670.00	4,300.00	4,300.00
Variable costs	73,704.44	74,135.24	74,566.04	74,996.84	75,427.64	75,858.44	76,289.24	76,720.04	77,150.84	77,581.64	78,012.44	78,443.24
Total costs	0.00	12,082.02	24,164.04	36,246.06	48,328.08	60,410.10	72,492.12	84,574.14	96,656.16	108,738.18	120,820.20	132,902.22
Net profit (loss)	(73,704.44)	(63,053.22)	(52,402.00)	(41,750.78)	(31,099.56)	(20,448.34)	(9,797.12)	7,054.10	16,405.28	25,756.46	35,107.64	44,458.82

Conclusions:

Please note: This analysis does not take into account time constraints or accelerated bonuses mentioned in the Accelerated Start-Up and Screening sections. We calculated the estimated FTE cost (excluding meals) for all personnel and have included it as fixed costs.

Based on this analysis:

- If no subjects are recruited into the study, the study will run an estimated deficit of \$73,704.00
- If subjects are recruited but not enrolled in the study it will still run at a deficit estimated between \$50,350 and \$67,028

In order to break even, the study must recruit and enroll a minimum of two subjects. We can potentially break-even with the enrollment of one subject if it now costs \$36,850 per subject.

2022 OCR Research Opportunities

Research Opportunities
Received

259

Research Opportunities
Accepted

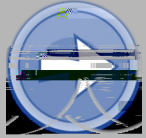
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Research Opportunities
Declined

9

declines due to staffing,
resources, competing trials,
not interested

Next Steps

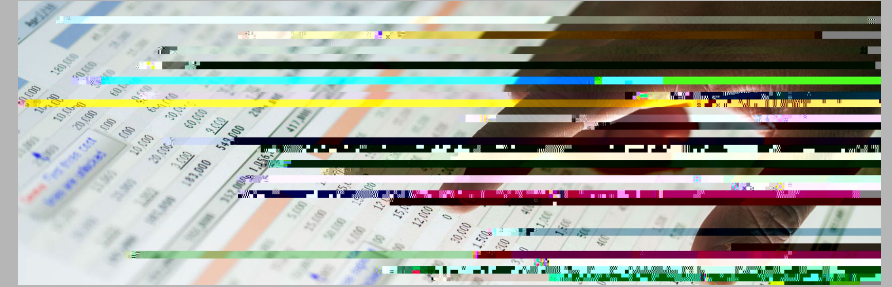


Department engagement

- Clinical Trial Liaison Proposal
 - Quarterly Meetings
 - Identification of areas of strategic importance for research
 - Identification/Outreach to junior investigators
- Quarterly Reports
 - Summary of Clinical Research Opportunities
 - OnCore Metrics



Research Financial Services



- Pre-Award Services: Medicaid/Medicare coverage, analyze the study cost and timeline, negotiate budgets with sponsors, and enter budget information into OnCore.
- Post-Award Services: Invoicing, revenue reconciliation, review of subject accounts, Participant Payments, and more.

OCR Finance Service Line ROI

- Data collected on 21 of the OCR serviced accounts
 - Pre-award
 - Baseline vs Final Negotiated Budget

Initial Sponsor Budget	OCR Negotiated Budget	ROI
\$864,585	\$2,381,675	\$1,517,090

