



GPC Pricing

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GPC Infrastructure Cost Recovery (= NAF, Network Access Fee)

- Infrastructure cost recovery (ICR)

GPC Products and Services

- Analysis as a Product
- Data as a Product
 - For Non-Profits like NIH/NLM and other collaborators
- Legal/Regulatory/Contracting
- Prospective trials and surveys
- GROUSE Environment

GPC Support Mechanisms

- GPC Pilots
- Letter of Support

Infrastructure Cost Recovery

Infrastructure Cost Recovery

- GPC charges 10% Infrastructure Cost Recovery (ICR) per year on the direct costs of the award for the portion that uses GPC resources. This is for Nonprofit/Academic projects to recover and provide for the ongoing data infrastructure.
- GPC currently proposes an initial 75% site – 25% GPC coordinating center split of the fees (ICR, GROUSE fees, but not direct effort), aligned with national processes to divide up the ICR between CC and CDRN/sites
- From the PCORnet national discussion, commercial contracts ICR should be assessed differently, because of the lack of budget transparency on commercial projects.

Infrastructure Cost Recovery (Cont.)

ICR Baseline

- Recommendations for ICR baseline where we have budget transparency (e.g. NIH RFA)
 1. 10% of direct costs of the portion project that uses GPC resources or
 2. \$1,000/GPC site + \$1,000/GPC Central; Whichever is higher.

Currently sites receive ~\$110,000 per year. As we move to less/no central support, we'd like to target a goal of \$60,000 minimum/year to be viable without subsidy by the site (this case assumes we would also reduce the effort for GPC participation below the PCRf Statement of Work)

1. MU as the GPC lead site and ROA team will conduct the assessment of which portion of costs use GPC resources versus a study that uses non-GPC resources (e.g. VA recruitment as well as GPC; 1st year is a planning year and no site involvement),
2. We suggest GPC supports and participates in proposals that cost recover infrastructure above a certain threshold (\$20,000 ICR or; \$50,000 total GPC cost). In general pilots should be conducted as single site activities. Exceptions can be made by the GPC Governing Council vote for GPC endorsed pilots.

Infrastructure Cost Recovery Example

Infrastructure Cost Recovery – DS INCLUDE

- Down Syndrome NIH Supplemental Grant - One-year duration
- Maximum \$500,000 direct costs
- Not all direct costs are shown.

Total Personnel		\$103,226
OTHER EXPENSES (i.e., publications, report costs, equipment rentals, etc.) (3% COLA incl.)		
PCORnet Infrastructure Cost Recovery	Fee to access multi-site data via PCORnet	\$50,000
Linkage with PCORnet and NIH	Data linkage with PCORnet, Self-determination.org, and NIH involving survey and data transfer	\$20,000
PCORnet Site Payments - 5 sites	IRB, Contract Execution, First Patient Incentive, Query and Closeout	\$112,500
Patient Recruitment	DS Connect \$20, SDI Survey \$20, Patient \$200, Patient Milestone @250 - \$20,000	\$140,000
Main Award Payments	Contract and Execution	\$34,500
Total Other Expenses		\$357,000

- Note: ICR distribution calculations are shown on the following slide.

Infrastructure Cost Recovery Example (cont.)

ICR– DS INCLUDE (Example)

If a PCORnet national study with CHOP and UPMC, estimated ICR distribution:

- 5% to lead site = \$2,500;

GPC payments - \$28,500 total (3/5th of \$47,500)

- KUMC: \$13,537.50 including \$7,125 for coordination (25% of \$28,500) plus \$7,125 as a site (1/3 of the remaining \$21,375) minus 10% * \$7,125 (GPC patient engagement at MU)
- MU: \$7,837.50 which is \$7,125 as a site plus 10% * \$7,125 (GPC patient engagement)
- Allina: \$7,125 as a site

Non-GPC site payments – \$19,000 total (\$9,500 each for CHOP & UPMC) (2/5th of sites)

- Network coordination payment to each site: \$2,375
- Site work payment to each site: \$7,125

Analysis as a Product

An example would be developing and executing a distributed analysis regarding blood pressure control in ambulatory clinics where code is sent to the sites in SAS, SQL, R. The underlying data stays at each GPC site.

Key Considerations

- Goal is to align with PCORnet overall pricing.
- Provided CDRN estimates for Low, Medium and High Complexity Projects
- Pricing is based on Non-Profit/Academic rates. Will adapt as necessary for commercial rates
- Continuing business development discussion with CAPriCORN.
- Hourly rates depending on personnel type range from \$85 to \$250 (which includes benefits and in-directs)

Analysis by Product - Summary

	Complexity											
Pricing for Academic Institutions and Non-Profit Organizations	Low <10 site hours				Medium (10-20 Site hours)				High (> 20 site hours)			
Coordination, Development and Execution at 12 GPC Sites	Low Range Hours	High Range Hours	Low Range Costs	High Range Costs	Low Range Hours	High Range Hours	Low Range Costs	High Range Costs	Low Range Hours	High Range Hours	Low Range Costs	High Range Costs
Coordination	75	175	\$ 15,000	\$35,000	225	350	\$40,000	\$60,000	400	650	\$65,000	\$100,000
Query development and validation												
Data aggregation and assembly												
Query run against GPC Data Marts												
IRB approval												

Data as a Product

An example would be sending code to the sites to define a blood pressure control cohort and the extracting the data for that cohort across several sites and sending the consolidated data to the investigator.

Key Considerations

- Rates apply when shipping data to a client.
- An “all-in” data table price is shown for the lead site and each incremental site which includes the tables listed.
- Pricing includes a data coordination fee, IRB and contracting and site selection fee for the lead site and participating sites.
- Pricing assumes a well defined computable phenotype for defining the cohort. If one does not exist or needs to be developed, analysis as a product hourly rates apply for coordination and analysis.
- Price is for a site level cohort size (< 150,000) but sending full tables (not picking columns which add cost to us). Pricing for larger cohorts will be evaluated on a case by case basis
- Suggest including a Co-I role for collaboration
- In the future we will develop a for-profit model if some partners are interested in providing that offering and corresponding sustainability
- We may also evaluate a revenue sharing (aka percentage based Infrastructure Cost Recovery) in the future.

Data as a Product

CDM Data Extraction and Delivery to Customer – Non-Profit Entity

- Additional CDM Tables* may not be available at all sites
- Other specialty data tables beyond listed tables will incur additional hourly and data costs depending on the source.
- IRB are bundled and may vary. This assumes de-identified data and use of GPC agreements.
- Conditions and restrictions apply (described the following page)

Data as a Product	Pricing for Non-Profit Entity retrieving patient cohort below 150,000/site	
	Lead GPC Site	Additional GPC Sites (per site)
Data Extraction, Coordination, IRB**, Patient Engagement, Contracting and Site Selection	\$5,000	\$2,500
CDM Tables - Basic, Core, and Study Specific CDM Tables*	\$10,000	\$5,000
Additional CDM and Other Specialty Data Tables	Hourly Rate + Data Fee	Hourly Rate + Data Fee

COMMON DATA MODEL TABLES
<u>Basic CDM Tables</u>
DEMOGRAPHIC
ENCOUNTER
<u>Core CDM Tables</u>
VITAL
DIAGNOSIS
CONDITION
ENROLLMENT
<u>Study Specific CDM Tables</u>
LAB_RESULT_CM
PRESCRIBING
DISPENSING
MED_ADMIN
PROCEDURES
<u>DEATH</u>
<u>Additional CDM and Specialty Tables*</u>
PRO_CM
OBS_GEN, OBS_CLIN
DEATH_CAUSE
PROVIDER
IMMUNIZATION
Tumor Registry, De-id Notes, i2b2 facts, etc.

Data as a Product (Cont.)

Conditions and Restrictions

- Assumes that data is de-identified and uses the GPC DSA and EICA.
- Data is not available for commercial use or resale. Commercial to be developed later among willing partners
- Hashed data for record linkages is additional specialty data and will incur additional costs.
- Identifiable data can be provided as part of a prospective trial where patients are consented.
- Data is only authorized for the specified use. Data re-use costs have been reviewed and approved by the GPC Governance Council and are currently set at 40% of the original data costs. Data re-use requests for special circumstances such as for public benefit will require review and approval by the GPC Governance Council.
- Proposed re-use costs:
 - Data costs with new study (40% of data costs assuming data as a product pricing)
 - Reuse processing costs proposed to be \$1,000 for the lead site and \$500 for each additional site.
 - GPC Governance Council reserves the right to assess re-use fees on an individual basis.

Data as a Product Example

Data as a Product		Lead Site Costs	Additional Site Costs	Number of Sites	Total Site Costs	Total Costs
Data Extraction, Coordination, IRB, Patient Engagement, Contracting and Site Selection		\$5,000	\$2,500	11	\$27,500	\$32,500
CDM Tables - Basic, Core and Study Specific		\$10,000	\$5,000	11	\$55,000	\$65,000
Total Data Costs		\$15,000	\$7,500		\$82,500	\$97,500
Data Re-Use - New Study	Percent of Original Costs	Lead Site Costs	Additional Site Costs	Number of Sites	Total Site Costs	Total Re-use Cost
Data Costs (60% discount illustrative only)	40%	\$6,000	\$3,000	11	\$33,000	\$39,000
Re-Use Processing		\$ 1,000	\$500	11	\$5,500	\$6,500
Total Data Re-Use Costs - New Study		\$7,000	\$3,500		\$38,500	\$45,500

Legal and Regulatory

IRB

- There is significant variability in IRB costs based on the study
- IRB must account for broader site services when providing cost data
- Have been past issues with “IRB shopping” to get minimum costs without a full understanding of the services.
- IRB organizations would like to include the following on the website:
 - Direct potential GPC collaborators to contact IRBs at institutions
 - Provide links to each of the GPC IRB organizations

Legal and Regulatory

Legal considerations:

- Establish baseline ranges for legal activities
- Effort differs based on lead or participating site
- Effort is reduced based on use of GPC External Institution Collaborator Agreement (EICA); Note that using limited or identified data will have increased costs due to IRB oversight.

Legal – Contracting Prospective Trial Estimate

Type of Work	Site	Major Tasks	Cost Estimate
Contracting and Start-up	Lead Site	Contracting and Start-up	\$16,000
	Participating Site	Contracting and Start-up	\$5,000
Close Out	Lead Site	Closeout	\$5,000
	Participating Site	Closeout	\$2,500
Use of GPC EICA	Lead Site	Use GPC EICA and De-Identified Data	\$3,500
	Participating Site	Use GPC EICA and De-Identified Data	\$1,000

Patient Recruitment and Milestone Payments

Key Considerations

- Should include reasonable costs for patient recruitment and patient engagement
- Should be graduated based on complexity
- Should be tailored to the nature of the study

Examples of Prospective Trial Contract/Data Milestone Payments

Type of Work	Site	Complexity	Estimates/ Examples
Patient Recruitment	Enrollment - Survey (Site Payment)	Low	\$300
	Enrollment with Follow-up (Site Payment)	Medium	\$450
	Enrollment - Randomized Drug Study (Site Payment)	High	TBD
	Patient Incentive Payment (Study Specific)	TBD	TBD
Enrollment Milestone Incentives	First Patient Enrolled	Per Site	\$2,000
	Proration of Patients Enrolled for Sites (Dependant on Number of Sites)	Proportional by Site	\$20,000
Study Specific Engagement	Study Specific Meetings and Follow Up	TBD	TBD
	Bonus Activities	TBD	TBD
CDM Query	Lead Site	Lead Site LOE	% Effort
	Participating Site (per query)	Medium	\$4,500

* Upfront funds may be required to launch a trial and are study specific.

Patient Engagement

Key Considerations

- Approach to Incentivize Patient Engagement Incentives/Rebates
 - ICR (10%) is being charged to maintain data infrastructure
 - The GPC central will set aside 20% of GPC central's fee to fund patient engagement.
 - Example: \$50,000 ICR from \$500,000 direct costs in Down Syndrome project (5 sites).
 - For this study, perhaps $\$50,000 \times 0.25 \times 0.2 = \$2,500$ will be used for engagement.
 - If the study was reviewed by the patient team and found to have sufficient patient engagement, we'd rebate this money to the lead site in GPC supporting the study.
 - If not, we'd offer support for study design, consent, recruitment, dissemination.
 - If they still decline, we may approve the study but would hold the PE funds to support PE infrastructure such as sending patients to the LEC, supporting them on calls, rebating money to patient input groups, etc

Patient Engagement

Key Considerations

- Patient Engagement Support
 - Estimates are that it will cost \$400 per rapid reactor session on remuneration of patient/community/PAC members
 - Need project management support of 5% FTE
 - Need facilitation support of 5% FTE
 - Estimated advocate support would \$60/hr per advocate
 - Food costs
 - IT or conferencing costs

GROUSE

GROUSE consolidates CMS claims across all GPC states along with the de-identified CDM and i2b2 data marts (containing tumor registries) from all the GPC sites.

Key Considerations

- Identifiable fixed annual costs
- Fees recover infrastructure costs
 - Continue to purchase new CMS data
 - MU and site teams to provide and integrate data
 - Additional NIST compliance and information security requirements
 - Hardware replacement
- Both Ruffed and Sage GROUSE have an ICR of 10%

Ruffed GROUSE Cost Estimates

Ruffed GROUSE (site data only – no claims)

- ICR of 10% of total direct cost should be included
- Cost distribution: 75% to participating sites and 25% for MU to recover maintenance cost
- Depends on the ability of each site to provide requested data.
- **Flat Fee for use of the Ruffed GROUSE environment: \$15,000 for the project**
- **Co-I: Strongly suggest including experienced GROUSE Co-I in project**

Ruffed Grouse Example

Example: NSF Submission with KU-Lawrence

- The total budget award is \$300,000 (direct + indirect) per year for 4 years.
- Will have collaborators from KU-Lawrence who will prepare their own budget per NSF rules. Note: Personnel budget for KUMC only.
- Includes ICR and Ruffed GROUSE data fees (where the Ruffed GROUSE charge is allocated over a 2-year time frame to spread out the yearly costs).
- Since the \$300,000 includes both indirect and direct costs, and our indirect rate is 53%, \$200,000 was used as the direct cost base with the resulting GPC ICR @10% = \$20,000 per year

	Year 1	Year 2	Year 3	Year 4
Total Personnel	\$66,377	\$68,367	\$70,420	\$72,533
OTHER EXPENSES (i.e., publications, report costs, equipment rentals, etc.) (3% COLA incl.)				
GPC ICR (10% of annual direct budget)	\$20,000	\$20,000	\$20,000	\$20,000
Ruffed GROUSE (PCORnet CDM tables)	\$10,000	\$5,000	\$0	\$0
Open access publication cost	\$0	\$6,000	\$6,000	\$6,000
	\$0	\$0	\$0	\$0
	\$0	\$0	\$0	\$0
	\$0	\$0	\$0	\$0
	\$0	\$0	\$0	\$0
	\$0	\$0	\$0	\$0
Total Other Expenses	\$30,000	\$31,000	\$26,000	\$26,000

Sage GROUSE Cost Estimates

Sage GROUSE (EMR + Claims)

- ICR of 10% direct total should be included
- CDM data cost is distributed to sites as per Ruff GROUSE pricing
- Fees collected from claims data and ResDAC data re-use application will stay with MU to recover cost for sustaining the claims data infrastructure
- **Flat Fee for use of the Sage GROUSE environment: \$25,000 for the project**
- **Data reuse fee, as applicable: \$5,000**
- **Co-I: Strongly suggest including experienced GROUSE Co-I in project**

Sage GROUSE Example – R21 with site data plus CMS

Grant Mechanism: R21				
Sage GROUSE Budget Worksheet - 10/10/2019				
Current Version: V1 - 10/2018				
Lemuel R. Waitman, Deandra Cassone, Xing Song / Medical Informatics, Internal Medicine				
Project Parameters needed for budgeting	Estimated Cohort size	less than 150K patients		
	Total number of participating sites	2		
	Effort requirement for Experienced GROUSE Co-I	10%		
Item	Item Description	Year 1	Year 2	comments
Overall Budget	R21 budget is between 275K to 200K for 2 years	\$ 125,000	\$ 125,000	Use a total of 250,000 for budgeting
Infrastructure Cost Recovery Total	10% of the annual budget	\$ 12,500	\$ 12,500	
# of participating sites	2	\$ 6,250	\$ 6,250	Not counted towards the total, just show how much distributed to the participation site
Site EMR Data Fee	PCORnet CDM tables (I2B2 tables are also available)	\$ 15,000	\$ -	Assuming the requested cohort include patients less than 150K. Only charged when new CDM data is requested
CMS reuse fee	All administrative work for CMS reuse (e.g. help put together re-use application and prepare IRB documents, answer inquiries from CMS)	\$ -	\$ -	Waived since Drew has already obtained an approval from CMS for data re-use
Sage GROUSE usage Fee	include data purchase and infrastructure expenses, as well as data linkage fee. Data is provided across all 7 years	\$ 25,000	\$ -	We are using the flat rate, regardless of type of patient cohort. Only charged when new CMS is requested
Experienced GROUSE Co-I	Flexible depending on involvement (5% ~ 20%). Use 10% as an average effort. Could increase if additional analytical support is requested.	\$ 12,000	\$ 12,000	This is the budget for having Xing Song be the Co-I. Don't count twice if her budget has already been considered
TOTAL		\$ 64,500	\$ 18,750	

This fee estimate is based on our understanding of the proposed data request. Any changes in this request, or clarification resulting in changes, may result in a change in the fee estimate. Additionally, this fee estimate reflects the current fees of maintaining the GROUSE data repository and infrastructure, which may be subject to change

Another Sage GROUSE Example

Grant Mechanism: R01							
Sage GROUSE Budget Worksheet - 10/10/2019							
Current Version: V1 - 10/2018							
Lemuel R. Waitman, Deandra Cassone, Xing Song / Medical Informatics, Internal Medicine							
Project Parameters needed for budgeting	Estimated Cohort size	less than 150K patients					
	Total number of participating sites	2					
	Effort requirement for Experienced GROUSE Co-I	10%					
	Additional Request	include identified data elements from local sites					
Item	Item Description	Year 1	Year 2	Year 3	Year 4	Year 5	comments
Overall Budget	Estimate based on R01 mechanism (\$500,000/year)	\$ 500,000	\$ 500,000	\$ 500,000	\$ 500,000	\$ 500,000	
Infrastructure Cost Recovery	10% of the annual budget	\$ 50,000	\$ 50,000	\$ 50,000	\$ 50,000	\$ 50,000	
# of participating sites	2	\$ 25,000	\$ 25,000	\$ 25,000	\$ 25,000	\$ 25,000	Not counted towards the total, just show how much distributed to the participation site
Site EMR Data Fee	PCORnet CDM tables (I2B2 tables are also available)	\$ 15,000	\$ 15,000	\$ 15,000	\$ 15,000	\$ 15,000	Assuming the requested cohort include patients less than 150K. Only charged when requesting new CDM data is requested
CMS reuse fee	All administrative work for CMS reuse (e.g. help put together re-use application and prepare IRB documents, answer inquiries from CMS)	\$ 5,000	\$ -	\$ -	\$ -	\$ -	
Sage GROUSE usage Fee	Include data purchase and infrastructure expenses, as well as data linkage fee. Data is provided across at least 2011 - 2017. We purchase and integrate additional CMS data on a yearly basis	\$ 25,000	\$ -	\$ -	\$ -	\$ -	We are using the flat rate, regardless of type of patient cohort. Only charged when requesting new CMS is requested
Experienced GROUSE Co-I	Flexible depending on involvement (5% ~ 20%). Use 10% as an average effort. Could increase if additional analytical support is requested.	\$ 12,000	\$ 12,000	\$ 12,000	\$ 12,000	\$ 12,000	This is the budget for having Xing Song be the Co-I. Don't count twice if her budget has already been considered elsewhere
Additional Data Element Integration	Integrate additional data elements from sites which are not currently collected in CDM or I2B2. It may require data management plan update with CMS, IRB modification, data de-identification and data linkage work at the hub site, as well as additional data collection work at participating sites	\$ 15,000	\$ 15,000	\$ 15,000	\$ 15,000	\$ 15,000	Need to assess how much work is required to integrate the identified data element, and whether de-identification is needed. Also need to know if this may happen every year for temporal data integration.
TOTAL		\$ 122,000	\$ 90,000	\$ 90,000	\$ 90,000	\$ 90,000	

This fee estimate is based on our understanding of the proposed data request. Any changes in this request, or clarification resulting in changes, may result in a change in the fee estimate. Additionally, this fee estimate reflects the current fees of the GROUSE data files, which may be subject to change

GPC Pilots

The GPC Governing Council on a case-by-case basis will approve pilots that go below infrastructure cost recovery threshold (\$20,000 ICR or; \$50,000 total GPC cost) and waive indirects but recover salary and fringe.

Pilots need to have

- Identified RFA or leading to submittal of an R01 size award.
- The larger award would support network sustainability >\$100,000
- Written commitment from investigators that they will use GPC for larger study

Letter of Support

Studies that meet the cost recovery criteria or are a GPC endorsed pilot can receive a letter of support from the GPC

- An ICR of more than \$20,000 or more than \$50,000 total GPC cost
- Templates can be provided
 - Project description
 - Confirmation of use of GPC and alignment and specific mention of the funding
 - Relevant Co-I's etc.
- GPC will provide narrative in the methods and resource sections of the proposal.
- We are also working with the GPC Patient Engagement Officers and Patient Advisory Council to consider developing a complementary Patient Engagement Letter of Support which would highlight it has been reviewed by GPC PEO/PAC and may highlight the engagement components in the proposal