

Clinical Reimbursement - Keeping Everyone Happy

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In the course of various conferences, symposia and manuscript review for *Applied Clinical Trials*, one manages to keep abreast of current issues and concerns in the clinical research arena of the Life Sciences, as well as time-worn chronic points of contention are areas fraught with difficulty. In the latter bucket is usually found clarity of regulations, ownership of data & publication rights, issues with standards, and of course finding and retaining good investigators/sites, amongst other things. This latter, acquiring and maintaining “good” sites, is a multi-faceted issue encompassing an extensive array of variables and dynamics, which in the final analysis all impact, either positively or negatively, on Sponsor-Site relationships. Of all the factors that could influence those relationships for good or ill, none is perhaps more potentially contentious than payments, and it is for this reason, along with increasing regulatory scrutiny, that clinical reimbursement is the topic of perennial discussion and concern - and rightly so.

The Problem

Few things can damage relationships with Investigative Sites as much as delayed or erroneous payments for services rendered in conducting Clinical Research - perhaps even more so than in years past as the economic downturn continues to wreak havoc across the world. Beyond that, as important as those relationships are, anti-kickback statues and Department of Justice activity have both placed Investigator payments under close scrutiny - a degree of precision and accountability is required now as never before.

One industry analyst report - “Managing clinical investigator compensation” by [Cutting Edge Information](#) opens with the following -

“The Pharmaceutical industry’s commercial relationships with physicians and thought leaders have fallen under intense scrutiny. The OIG [Office of Inspector General], Congress, state legislatures and consumer advocacy groups have all decried what they view as unethically and insidiously harmful partnerships...

...companies such as Pfizer, Merck, Eli Lilly and Medtronic [are] bowing to public pressure and the spectre of the Physician Payments Sunshine Act...

...scrutiny and regulation are poised to start trickling over into the clinical side of physician-industry relationships, most specifically concerned with compensation of Investigators leading clinical trials.”

Given this state of affairs, it would seem imperative that organizations pay close attention to research reimbursement issues as a matter of some urgency - but some years as a clinical/business consultant indicate otherwise. The simple fact is that the majority of sponsors utilize a corporate payment system ill-equipped to deal with a multitude of highly variable payments: they are fundamentally predicated on a payment system whose basis is receipt of invoices from vendors - be it office furniture, parts, computers, whatever - and not payment of reimbursement to clinical researchers.

As it is rare, or at least uncommon, for sites to send invoices for research services such as follow-up visits and the like, the task of generating payment usually falls to a CRA in the clinical department to create a cheque (US="check") request - and that involves going through site activity, on an individual basis, and checking what is eligible for payment and what isn't, and what has been previously paid or denied - in essence, creating an invoice. This activity is not their core skill-set, so the process takes a little longer than it might say, for the accounting department - but then they'd never go to this level of work to pay a vendor anyway. As money is involved, someone has to check the work of the first CRA, and then someone else checks it again to authorize - that, however, is not the end of the story.

The cheque request now has to go over to accounting, they have to enter it into the corporate system, the system spits out a cheque (eventually) and someone else goes through those documents and sends them to the right departments. In the case of the clinical department, they have to then match the cheque to the account, make sure what was requested was what was produced, then create a mailing label and then send the funds. All of this takes a lot of time and effort during which there a multitude of opportunities for things to go wrong, and all the while the Site is waiting for payment. God forbid there should actually be something wrong when they get their money, as so many people are involved with multiple systems and pieces of paper it can take days for a simple query to be resolved – we've all seen it happen.

Potential Solutions

So between a high burden of work, lengthy times to execute, high potential for error and difficulty in troubleshooting putting mechanisms in place to make everyone's lives easier would seem to be a priority – but what's the answer? Short of deploying an enterprise-wide CTMS, with all the expense and support issues involved at first glance no "simple" answer appears to exist – unless, of course, you just happen to have the right EDC/eClinical tool. Reimbursement is one of those areas where the line between EDC/eClinical and CTMS has begun to blur, and blur significantly in some instances. Why this is, and the challenges and benefits of such developments is another paper, but suffice to say that in most cases you can get >90% of a CTMS's capabilities out of a decent EDC/eClinical system for a fraction of the cost – as in single digit percentage points, and in some cases, no additional cost at all: the CTMS-like functions are simply a by-product of system operation.

With respect to payments, the concept of EDC/eClinical system driven reimbursement is hardly new - there's a patent application floating around somewhere with my name on it for such a thing from way back in early 2004 in fact. Competition, and advancing technology however, has in the space of 5 or so years produced far more sophisticated systems than our primitive design, although it is still in use in some places. Not all EDC systems offer reimbursement capabilities, and as the implementation of our early design shows, not all reimbursement systems are created equal.

Requirements for a *good* solution

Before examining one such system from Prelude Dynamics, we should specify exactly what is needed in a good reimbursement system as opposed to merely adequate one, and rank Prelude's offering accordingly -

- Automaticity
 - The system should automate as many manual processes as possible to reduce both personnel burden and margin for human error
- Flexibility
 - Visit payments are but one of the many reimbursable events within clinical research. The system should allow for payments related to -
 - Screening
 - Testing - blood draws, ECGs, treadmill test, etc. AND allow for additional payments for extra tests if clinically necessary as a result of the research (or findings of the initial test)
 - IRB fees, including submission, evaluation & annual renewal
 - Patient travel expenses/participation fees
 - AE/SAE/UAE events
 - Et cetera
 - Payments should be able to be varied between different sites to allow for regional variations in Fair Market Value
 - Capability for partial payment for incomplete visits/optional testing should be included

- Adaptability
 - Few company's financial procedures are identical, so a good reimbursement system should be able to adapt to your processes and workflow, and not the other way around (and not cost an arm and a leg to modify either)
- Visibility/Transparency/Accessibility
 - Comprehensive reporting on payments
 - By Study, Physician, Site internally
 - To Sites, Physicians, Other
 - In order to provide timely customer service in the event of a query, the system must allow for a high degree of ad hoc reporting quickly and easily
- Security
 - Payments should only be visible to those systems users who have a need to know the information
- Predictability
 - It is a fundamental requirement that the system be reliable and predictable in operation in order to deliver automaticity - validate-once/use-many (perhaps "forecasting" or "projections" may be better terms). Thus, in this instance, predictability relates to the ability of the system to use information adaptively to predict future spend and liabilities-
 - for example, by taking the enrollment rate (based on sites online and coming online (rate modeled in the latter) plus the existing rate of AEs plus visits scheduled to take place within the next reporting period (say, one quarter) minus the know LTFU, missed visit and mortality rate multiplied by the various applicable payment rates yields the projected liability for the next quarter or year or other period

Ranking the Prelude Dynamics “Vision” reimbursement module

Automaticity 4/5

Very little human intervention is required for the operation of the Vision reimbursement module – once it’s set up, it pays what should be paid and with-holds what shouldn’t. You can even have the system output a file for direct import in you SAP Financial system or JD Edwards or similar – validate the process once, use it over and over: margin for error decreases dramatically. Personnel burden drops significantly too: humans are good at *thinking* (well, some of us are), while machines are far better at repetition – and quickly too. If your personnel are spending their time going over CRFs and seeing if they’re eligible for payment, their neurons could probably be put to better use – the EDC/eClinical system *knows* what forms are complete and which have problems, so let the machine do the checking (should take a second of two versus days for a human).

Conveniently, Vision picks up payee details from other Investigator information already in the system and can even cross-check against financial disclosure and taxpayer ID receipt before releasing payment – which makes the government (and you legal department) very happy.

Why 4 out of 5? The current Prelude system requires Study Sponsor personnel to enter names for the payable events – the system knows the names already and should pre-populate these fields for you. The good folks at Prelude tell me that’s on the way.

#	Event	year from enrollment	Personnel		Travel	Tests/Rx	Supplies	Costs	
			Coordinator	PI				TOTAL	PLUS F&A
1	Screening	1	65	120	0	150	10	345	448
2	Visit 1	1	45	222	0	73	22	362	471
3	Visit 2	2	45	222	0	121	43	431	560
4									
Total Per Patient			155	564	0	344	75	1138	1479
Total Enrollments		140	Total for all Patients		207060				

Flexibility 5/5

If it were possible to give a 6 out of 5 this would be where it would happen. Take a look at the screenshots below – fixed costs, variable costs, breakdown split between personnel types, travel expenses, supplies and more. Better yet, all those can have individual level site variations, if needed – a significant limitation of other systems is that they tend to regard fees as homogenous – but the simple

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fact is it costs more for a Key Opinion Leader Investigator in New York City than it does in Kansas City: the flexibility of the Vision system is such that accommodating those variations is simple, and can be adjusted by you, the Sponsor – no programming required. Even better, standardized or proprietary codes can be manually or automatically assigned to procedures/events to enhance analysis and cost allocation.

Fixed Expenses									
#	Event	year/yearly	Personnel		Travel	Tests/Rx	Supplies	Costs	
			Coordinator	PI				TOTAL	PLUS F&A
1	Investigator Meeting	1 <input type="checkbox"/>	123	223	1000	0	0	1346	1750
2	Nurse Training/Regulatory	1 <input checked="" type="checkbox"/>	100	0	500	0	0	600	780
3		<input type="checkbox"/>							
Total Fixed Expense			223	223	1500	0	0	1946	2530

Exam Types Coding and Pricing			
Exam Description	Code 1	Code 2	Price
Office Visit-Ref. Consult	1100		\$ 100
Extended Recheck	1001	EX008	\$ 90
Brief	1004	EX010	\$ 40
Follow-up	1006	EX012	\$ 60
Recheck	1007	EC014	\$ 30
Office Visit-No charge	1010	EX022	\$ 0
Drain Removal			\$
Suture Removal			\$
Emergency Fee			\$
In Hospital Surgical Consult			\$

Labs Coding and Pricing			
Lab Description	Code 1	Code 2	Price
Total Body Function	2010	SA120	\$ 77
Super Chem, CBC	2019	SA020	\$ 66
Vet Screen, CBC	2020	SA030	\$ 55
Coag Profile			\$
Autoimmune Profile			\$
Bile Acids (Pre/Post)			\$
Complete Blood Count			\$
Creatinine			\$

Adaptability 5/5

It's difficult to cover this topic more succinctly than Dr Alicia Browner, one of the founders of Prelude Dynamics, did in a communication recently, so I won't try –

"...since sponsors may calculate their invoices differently, there is a need to be able to configure/tailor the invoices to the specific study.

For example, one customer didn't want the visits to show up on an invoice until the visit state was FINAL (i.e., all data entered and reviewed and locked), whereas other sponsors will pay as soon as the visit occurs.

Some sponsors want more granularity in the payments, whereas others pay a lump sum for a visit. And so on...

Anyway, for us, the invoice is just another "CRF" so to speak, and the sponsors can then reuse this form with subsequent studies, and it's tailored to their workflow, not Prelude's concept of their workflow."

Apart from the obvious adaptability, the last sentence is especially interesting. That's because such an approach is very efficient, and therefore cost-effective – and that's a good thing.

01-Dec-2008		Invoice 2		
Patient Events				
From: 24-Sep-1909 to 01-Dec-2008				
#	Description: Patient ID	Event	Date	Total
1	367GJK	Screening	10-Oct-2008	448
2	367GJK	Visit 1	01-Nov-2008	471
3	134PLW	Screening	10-Oct-2008	448
4	134PLW	Visit 1	01-Nov-2008	471
5	686ERW	Screening	10-Oct-2008	448
6	589IUT	Screening	10-Oct-2008	448
7	805OND	Screening	10-Oct-2008	448
Total				2286
Fixed Price Events				
#	Description	Event	Date	Total
1	Meeting Attendance	Investigator Meeting	04-Nov-2008	1750
2				
Total				1750
TOTAL FOR THIS INVOICE				4036

Visibility/Transparency/Accessibility 5/5

Simple and easy. In a couple of clicks, any Sponsor personnel can see exactly what was paid to whom, when, and what for. Time burden? Perhaps 30 seconds.

To compare and contrast, some years ago, a department that we were busily transitioning to EDC/eClinical had a few legacy paper studies floating around. About 18 months after the fact, one of our top sites, with a very important KOL, claimed they hadn't been paid for a series of visits on one of those legacy projects. What ensued, in trying to work it all out, took 1 person about a week and going back and forth between the CDMS, finance, paper CRF copies (study was closed, so they were archived), reconciling various excel spreadsheets, et cetera. Plus a few hours of management time reviewing findings and communicating with the customer. I'm guessing that with overhead that one activity cost the department about \$2,000 including overhead.

To stay out of hot water with regulators, Vision can even automatically produce roll-up reports showing at in aggregate where the money went, including across different studies or even sites – many physicians will enroll at more than one place. The automaticity of this function is such that it takes no time at all – it just happens.

Security 5/5

The next worse thing to not paying someone for work performed is to let their financial details be known to those who have no business knowing it. Some sites are very open amongst personnel about reimbursement, while in others, physicians often don't want their RC's seeing how much they're getting for each visit (especially if the RC collected all the data). For that matter, why should monitors or data managers, for example, be able to review site/investigator reimbursements?

Vision, like any modern EDC/eClinical system, has a variety of configurable user-types, which are usually classified by function – RC, PI, CRA, Biostat, Monitor, etc. Which users get to see financial details is a very simple matter of specifying during study development what they should have access to.

User-types are common – robust security less so. Some well-known systems suffer from a very simple vulnerability – URL keying. What can, and does, happen, is that unauthorized personnel either type modifiers onto a URL that allows them to see a page they shouldn't (once they're in the system, for which they might be authorized for some other function), or they simply look at the browser history on

a shared computer – common in clinical settings. For example, they may type “site_payment.html” on the tail end of “www.yourstudy.com/protocol458/mercyhosp/” Try doing that with Vision and see how far you get.

Predictability (financial) 4/5

Figure 2 shows an example of financial liability prediction/projection over time with line item totals and roll-ups by year. A degree of modeling is afforded by altering # sites enrolling, and patients enrolled per year. If contracts need to be renegotiated as years progress (think registries, but some longer running approval trials too), that can be accommodated on a site by site or study level from a fixed point in time forward. These relatively simple concepts make that “site payments” part of your budget projections around October each year much faster, easier, and arguably more accurate. Surprisingly, many systems that offer some form of reimbursement fail to take this next step, however.

Site Budget			
Budget Item	year 1	year 2	
Fixed Costs			
Coordinator	223	100	
PI	223	0	
Travel	1500	500	
Tests/Rx	0	0	
Supplies	0	0	
Total per Site	1946	600	
Total per Site plus F&A	2530	780	
# Sites Enrolled: 3	7590	2340	
Enrollment Costs			
# Patients Enrolled	100	40	
Coordinator	11000	8900	
PI	34200	35880	
Travel	0	0	
Tests/Rx	22300	21020	
Supplies			
Total	70700	71380	

Given the utility of this aspect, why the down-check to “4/5”? Every clinical manager knows how much their management loves nice financial graphs on PowerPoint – so why not make that available here? In addition, the higher order function of what might be termed “dynamic self-adjusting projection” is not present. It may be a little unfair, because few, if any, others offer it either, but why not use the data the system has already captured to dynamically alter the projection based on the known rate of enrollments, LFTUs, withdrawals, deaths, etc etc? Such a characteristic would enhance the accuracy of the projection and thus further streamline the budgeting process. At the next level, the system would take metrics derived from the real-world experience of prior studies, especially if the same investigative sites are used, and provide projections very early in the deployment process for new studies – allowing not just a high degree of predictability to cash-flow, but also enrollment, drop rates and other key timeline impacting events.

A Few Closing Thoughts...

A reimbursement module operates on the simple principle that a good system knows what payments are due and not due at any given point in time. Smart software developers use that principle to save you money, time and frustration and do all sorts of things with it. In Prelude's case, related to money is the activity log - this is a mechanism that captures how long people are spending on CRF pages,, and automatically filters out "click-throughs " (meant to go there, ended up here by mistake, click-through to "there" in a few seconds) as well as those instances where users have obviously walked away from their computer at some stage. This report/log gives you some very powerful information that you can use to –

- Detect and review "problem" CRFs that are taking significantly longer than the median to complete
- Obtain data you can use in contract negotiations about the burden actually put on site personnel for study data entry
- Keep an eye on field personnel – forms monitored on-site huh? How come it only took 2 seconds per form (about the time it takes to sign off) to perform that task?

A quality, built-in, reimbursement system has so many benefits associated in terms of efficiency, customer satisfaction and compliance, *why wouldn't* it be part of your EDC/eClinical provider selection process? Appropriately addressed, clinical reimbursement can not only keep everyone happy, but actually enhance Sponsor-Site relationships into the bargain - especially if the other Sponsor's vying for your sites' time reimbursement issues, and many do.

Like almost everything in this space, however, one man's "quality" reimbursement module is another's excel spreadsheet online: product characteristics and capabilities vary tremendously between providers. So, rather than just checking a box next to "reimbursement" on your checklist, think through what you want and need from the feature in terms of automaticity, flexibility, adaptability, visibility and predictability – and don't forget to check for simple security problems along the way.

PRELUDE DYNAMICS, LLC— founded in 2003, and located in Austin, Texas, is a premier provider of Electronic Data Capture (EDC) and Data Management (DM) software systems and services.

Vision is a robust, web-based, regulatory-compliant clinical data management application used both for data collection at clinical sites and for workflow and trial data management. Vision was developed by engineers with many years experience in developing rigorous software systems for NASA and the Department of Defense, and they brought that same rigor and standards to the clinical trial industry.

Prelude's Vision has been successfully deployed on dozens of regulated clinical trials for pharmaceutical, medical device, and biologic companies. It is used in 18 countries around the world, including the U.S., Canada, France, Germany, Australia, India, Spain, Brazil, Puerto Rico, Israel, and Turkey.

Dr Timothy R.H. Pratt, PhD - is a well-known figure in the Life Sciences clinical industry, and was voted to the top 100 "most inspiring in Life Sciences" by Pharma VOICE readers in 2005. A prolific publisher and speaker, Dr Pratt leverages clinical research and business experiences gained over 25 years and in countries such as Australia, Canada, the UK, the USA, France, Holland, Germany, Italy, Spain and others. His Life Sciences focused education which includes a PhD, 3 Master's degrees, and a number of specialist post-graduate qualifications complement an enviable history as a clinician and helps him provide unique and penetrating insights into efficiency gains in the clinical research process, marketing, and business operations.

Multi-awarded at the divisional, country and global level by several Fortune 500 companies, Dr Pratt has helped organizations large and small, providers and manufacturers/sponsors, to implement new processes and technology, redevelop clinical strategies, assess and retain talent, develop support materials and much more on a consulting basis since 2003.

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