

What a Lead Programmer Does for effective project management of programming activities under various outsourced models

Innovation



Quality



Flexibility



Agenda

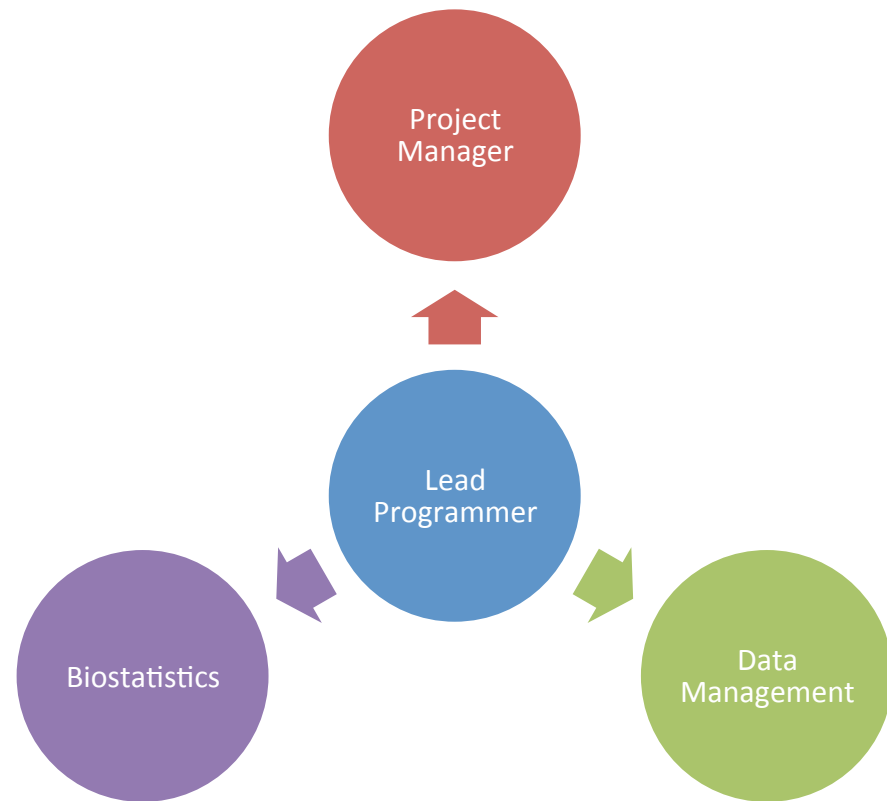
- Understanding the Operating Model Impact
- Defining the Various Operating Models
- Project Management Responsibilities
- PM Disciplines and Tools
- Maximizing Tools

Disclaimer

- The environment and needs of each programming team vary between clients and providers. Many of the principles are consistent across the clinical research industry but it's important that lead programmers are attune to the variations of implementation
- This presentation intends to provide considerations for programmers, statisticians, and managers that are responsible for the oversight of the statistical outputs although many of these considerations are also applicable to other functional responsibilities
- One size does **not** fit all

Understanding the Operating Model Impact

The good old days...



Today...



Everyone wants to know...



- Are you going to meet the delivery timeline?
- Are you on budget?
- What % of the work is done?
- Are you managing proactively?
- What are the risks and issues and where can management help?

- How do you know for sure?
- Does everyone have a consistent update?
- With distributed resources, how current is your information?

Defining the Operating Models

- **Project Contract:** individual study contracts that are assigned to a single CRO or to multiple CROs based on functional area such as biostatistics, data management, and clinical operations. PM may or may not work with same provider as other functional areas.
- **Preferred Service Provider:** partnerships where entire projects are sourced in bulk to CROs. With PSPs, typically an entire project has been assigned to a single organization. PM generally works with same provider as other functional areas.
- **Functional Service Provider:** partnerships where individual functional areas are being serviced by CROs. These CROs may have more than one service for a study but often each functional area may have a different provider. PM usually does not work with same provider as other functional areas.

Understanding the Operating Models

- Why and how does the operating model impact the Lead Programmer on a study?
 - Scope of the Lead Programmer's responsibilities
 - Determines the relationship with the statistician (same or different organization)
 - More project management responsibilities in FSP relationships
 - Model determines who will need project reporting and communications, for example:
 - Study team
 - Line management
 - ***Functional management (provider and pharma)***
 - ***Relationship governance (FSP / PSP)***
 - Model impacts the standards and tools that exist for project management
 - Timeline reporting standards
 - Communication plan
 - Risk and issue management
 - Inventory files
 - Service Level Agreements
 - Programming standards inherently impact the management

How to understand the model

- Read the contract
 - Understanding the model has significant bearing on the effectiveness of project management (FTE, deliverables model, time and materials)
 - **Caution:** Master Service Agreements, Work Orders, and Change Orders may require redaction or summarization for programming teams
 - Invoicing expectations
 - Project scope documents (contractual or as guidelines)
 - Responsibilities matrix (FSP / PSP)
 - Reporting requirements
 - Service level agreements are important to understand
- Collaborate with management
 - Additional client expectations may be in progress
- Governance manuals
 - Detailed operational expectations

Project Management Responsibilities

- Many Lead Programmers are also technical leads however the following are the PM disciplines they should understand
 - Project management (plan)
 - Scope management
 - Time management
 - Cost / budget management
 - Quality management
 - Resource management
 - Communications
 - Risk \ issue management
 - *Procurement*
 - *Stakeholder management*
- For more detailed project management methodology please consider visiting www.pmi.org

Project Management Plan

- Overall project expectations – in clinical research typically combines functional services (Clinical, DM, Biostat)
- Typically created by the overall PM for the clinical study
- Lead Programmer should be familiar with the contents of the overall project plan

Scope Management

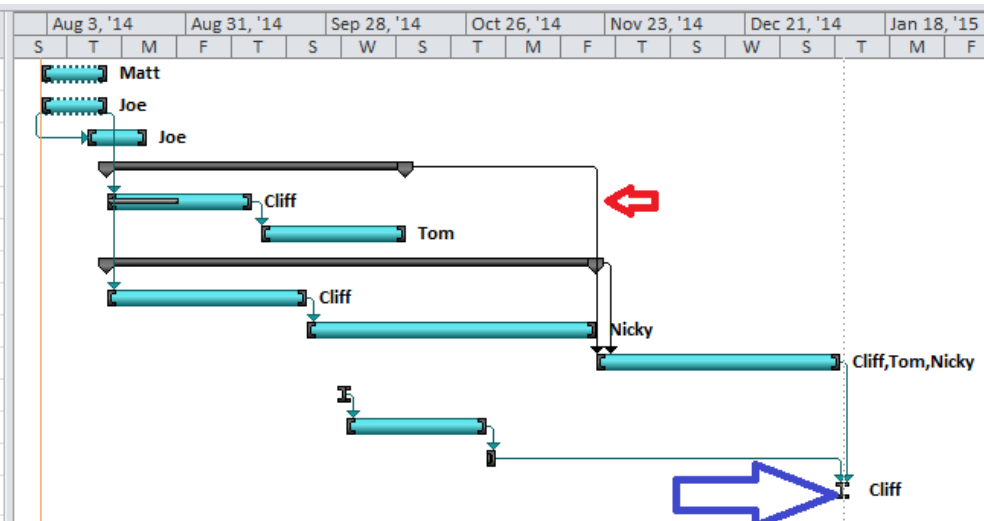
- Scope may be defined in a project specific work order, scope document, RACI chart
- Programming responsibilities should be clear and understood at project initiation. Consider efficacy programming/QC, patient profiles, data export, standards being applied
- When programming and statistical responsibilities are performed by different organizations the lead programmer and statistician should agree on the scope
- SDTM, ADaM, Tables, Listings, Graphs
- Are TLGs programmed against SDTM / ADaM
- A lead should be able to track changes to the scope over time (consider Excel or inventory spreadsheet)

PM Disciplines and Tools

Time Management

- Excel or PM tool such as MS Project allow for easy what-if analysis
- Use Predecessors, Durations, and % Complete
- MS Project can also be used for project resource management
- Task considerations:
 - Focus on your tasks but align with global timelines to ensure consistent reporting
 - Other functional timelines (clinical, DM)
 - Client and environment standards
 - Multiple review cycles in tasks

Task Name	Duration	Start	Finish	Predecessors	% Complete
Clinical DB Creation	2 wks	Sat 8/2/14	Thu 8/14/14		0%
SAP Creation	2 wks	Sat 8/2/14	Thu 8/14/14		0%
TLF Specifications Creation	2 wks	Mon 8/11/14	Fri 8/22/14	2SS+5 days	0%
SDTM	42 days	Fri 8/15/14	Mon 10/13/14		25%
SDTM Specifications	21 days	Fri 8/15/14	Fri 9/12/14	2	50%
SDTM Programming	21 days	Mon 9/15/14	Mon 10/13/14	5	0%
ADaM	70 days	Fri 8/15/14	Thu 11/20/14		0%
ADaM Specifications	28 days	Fri 8/15/14	Tue 9/23/14	2	0%
ADaM Programming	42 days	Wed 9/24/14	Thu 11/20/14	8	0%
TLG Programming	35 days	Fri 11/21/14	Thu 1/8/15	4,7	0%
Subject Enrollment Met	1 day	Wed 10/1/14	Wed 10/1/14		0%
Last Patient Visit	20 days	Thu 10/2/14	Wed 10/29/14	11	0%
DB Lock	2 days	Thu 10/30/14	Fri 10/31/14	12	0%
Final TLF Delivery	1 day	Fri 1/9/15	Fri 1/9/15	10,13	0%



Cost / Budget Management

- **Fixed Price Contract**
 - Scope defined / estimated at beginning of study
 - Changes to scope require change orders
 - Lead Programmer needs to understand the contract so that the changes can be tracked accordingly in Excel or scope tracking system
- **Time and Materials**
 - Provider is paid for each hour of effort
 - Timesheet system used for invoices
 - Lead Programmer should understand the budgeting expectations with client
 - Pressure on estimations for the study budget
- **Resourcing / Full-time Equivalent**
 - Similar to T&M however non-project costs are also included
 - Rates calculated differently
- **Considerations**
 - Know the timesheet system and reports
 - Consider the level to which timesheet data is tracked. It seems like a good idea to collect time associated to individual TLG however the accuracy is often best assessed at a higher level

Quality Management

- **See SOPs for quality management requirements**
- **Project Management Considerations**
 - Ensure QC steps are included in the project timelines
 - Ensure independent QC programmer is resourced
 - Include Quality in Risk Management exercises
 - Inventory files
 - Many environments utilize spreadsheets / inventory files to incorporate headers and footers
 - Consider incorporating status of each delivery
 - Careful not to impact the GCP process
 - Data can be utilized for status reporting

Resource Management

- Good
 - Project assignments
 - Tend to be more detailed but more difficult to manage large resource pools
- Better
 - Manager-level resourcing
 - May be managed at assignments level but limits the assessment of global resources
- Best
 - Department resource management that is shared across teams
 - Tracking by region, project, resource, month (week), and item
- General
 - Appropriate tracking depends on the number of programmers. Larger teams can have greater fluctuations that require higher degree of resource management
 - Resource assignments by programming task can create an experience database

Resource Management Example

Capture the data you want in Excel, MS Project, ERP

- Difficult to manage file based systems with multiple resource managers. Be sure to have version control enabled if possible.
- The lower level the data, the more difficult it becomes but the greater the return for management of larger resource pools

Project	Employee	Assignment	Role	Aug	Sep	Oct
CCC-001	Matt	ADaM	Production	45	45	
CCC-001	Joe	SDTM	Production	60	60	
CCC-001	Matt	ADaM	Production	45		15
DDD-033	Matt	ADaM	Production	15	15	
DDD-033	Joe	ADaM	QC	60	60	
DDD-033	Joe	SDTM	QC	60	60	
DDD-033	Unassigned	SDTM	Production	120	120	
DDD-033	Unassigned	SDTM	QC	15	15	

Realistically assess your needs within your global teams

Staff Workload

Row Labels	Sum of Aug	Sum of Sep	Sum of Oct
⊕ Joe	180	180	
⊕ Matt	105	60	15
⊕ (blank)			
⊖ Unassigned	135	135	
DDD-033	135	135	
Grand Total	420	375	15

Project Needs / Budgeting

Row Labels	Sum of Aug	Sum of Sep	Sum of Oct
CCC-001	150	105	15
DDD-033	270	270	
Grand Total	420	375	15

More considerations

- Add regional assignments
- Combine workload with other data (timesheet system exports, inventory files)
- Look for gaps and over assignments for personnel
- Collaborate with other teams to fill gaps

Communication!

- **Number 1 expectation of study teams**
- Document it in a plan (study team plan)
 - Cross functional team members (who)
 - Escalation paths
 - Meetings expectation (attendees, frequency, purpose)
 - Ownership for action items and risks (logs)
 - Escalation paths
 - Communication preferences (email, phone, IM)



Risk Management

- Planning for potential issues and should have a specific process:
 - **Identify**
 - Brainstorm **all** areas of concern (resource availability, timelines, therapeutic specific nuances, budget)
 - Collaborate with programmers and statisticians regardless of the model type
 - **Analyze**
 - Classify probability and impact of each risk (such as 1-5 or Red/Amber/Green scale)
 - Rank risks based on classifications
 - **Plan**
 - Create mitigation strategy for each risk (programmers on standby, weekly team meetings,
 - Understand triggers to implement mitigation strategies
 - **Implement**
 - Manage the strategies agreed upon
 - **Track and Control**
 - Monitor and report risks and mitigation strategies with team
 - Dedicate time to risk management
- **NOTE: different teams have different risk tolerances**

Risk Management Example

Category	Risk Description	Probability (P)	Impact (I)	RAG (Calculated)	Risk Response Plan
Resources	Lead programmer anticipates being on holiday during the delivery date of the final TLFs	Medium	Low	Green	Joe has been the backup lead programmer, has been attending all team meetings, and is being CC'd on all important communications.
Timelines	Five studies are due to be delivered during December however these are based off final enrollment. If all studies do align to that timeline resources will be constrained.	High	High	Red	Additional resources have been identified to assist. Work has been pulled forward on 3 of these studies
Communication	Global team across 8 timezones and 3 companies is supporting this program so communications may be delayed	Low	High	Green	Weekly meetings will be established

Maximizing Tools



Maximizing Tools

- Inventory Files
 - Files that maintain a list of all study deliverables (CDISC domains, TLGs) are natural locations for storing the status of each deliverable
 - Status can be updated by the individual programmer
 - Consider utilizing for % complete reporting
 - Be careful not to impact TLG deliveries by adding status data
- Project Website
 - File management / central repository
 - Access to teams across organizations and levels
 - Websites (such as Sharepoint) are basic data collection engines that allow for the export of data into spreadsheet format
- Email
 - Consider placing deadlines in your calendar
 - Reserve time on your calendar for PM activities

Maximizing Tools

- MS Project
 - Timeline management as well as what-if analysis of timeline shifts
 - Can be a resource management tool in some environments
- Finance / Timesheet system
 - Most systems have many reports that allow live access to project driving data such as hours spent, % complete, and timelines
 - Burn down of resource hours can be performed using timesheet data
- Excel
 - Spreadsheets offer significant flexibility for customized reporting
 - When data is collected in other systems it can be included in Excel for quick analysis
- SAS
 - You know it, use it

Questions?

For additional questions please feel free to contact me directly at James.Gunter@chiltern.com