



Working Model for Effective Functional Service Provider (FSP) Collaboration

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Disclaimer and preface

- Views, opinions and thoughts are my own and do not necessarily reflect those of my employer and colleagues
- I welcome interactivity during this presentation – please ask a question during the talk if something is not clear or raise a comment if relevant

About Me

- 17 years in the industry doing statistical programming
- 2 companies
- Currently functional head of statistical programming
- Issues in focus
 - Reporting system and standards implementation
 - Validation methodology for statistical analysis programming
 - Outsourcing/offshoring/remote working models
 - Training and change management
 - Clinical trials data transparency and disclosure

Agenda

- Company and history with statistical programmer resourcing
- Offshoring → Functional Service Provider (FSP)
- Development of a working model
- Implementation and experiences/challenges
- Lessons learned and continuous improvement

Company

- Vaccines is one of several divisions within Novartis
- Globally dispersed organization of 6,500+ employees
- Data management primarily outsourced
- Statisticians and programmers in 5 countries incl. outsourcing
- History



Geography of Biometrics Staff



Yellow = FSP staff

Programmer Resourcing Across Time

Period	Organization	Structure
1	Chiron	Permanent + Contractors (separate Prog dept)
2	Novartis	Permanent + Contractors + Offshore (separate Prog dept)
3	Novartis	Permanent + Strategic Provider Offshore FSP Strategic Provider Contractors (perm. integrated with Stats)

Variations of external resourcing

Structure	Characteristics
Contractors (agency or independent)	• Hourly or Time and materials (T&M) based • Resource and performance management by sponsor • Works in sponsor's systems and processes
Project Outsourcing (aka full outsourcing)	• Deliverables based (unit costing) • Resource and performance management by CRO • Detached working model with sponsor oversight • Works in CRO's systems and processes
Functional Service Provider (FSP) Outsourcing	• <u>Can</u> be T&M or deliverables based • Resources and performance <u>can</u> be joint management by sponsor and CRO, or management by one side • <u>Can</u> be fully attached, semi-detached, or attached working model • <u>Can</u> work in sponsor systems/processes or CRO's

Key logistics

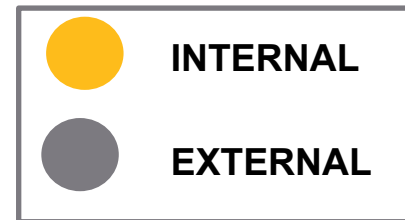
- FSP staff uses CRO equipment
- FSP trained on subset of Novartis processes
- FSP works on NVx SAS system
- Management of daily work done by FSP
 - Recording daily effort on analysis tasks to enable future forecasting model
 - Responsible for meeting timelines with quality
- Establish “train-the-trainer” model
 - Training records maintained in CRO system
- Oversight of timelines, work, and quality by NVx
 - Some administrative tasks

Training

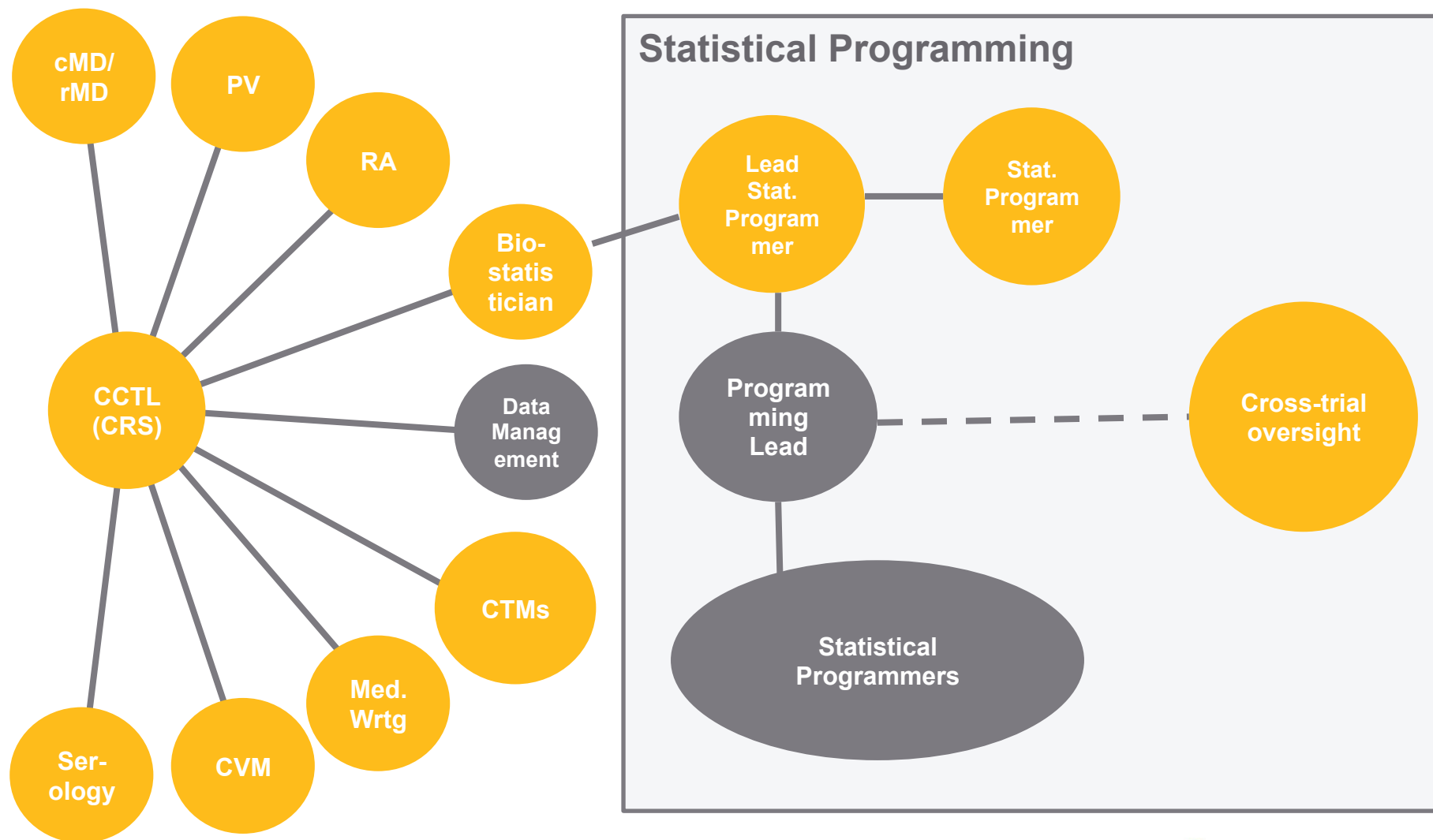
- Modes: face-to-face, webex, self-reading
- Subset of NVx process + all CRO trainings
- System and technical trainings
 - NVx programming environment (SDD)
 - Re-analyze a study to demonstrate comprehension
 - Establish “train-the-trainer”
- Align culture and develop the role skills
 - Communicate the key traits and expectations of the sponsor
 - Cultivate the soft skills for each role
 - Challenge elements (geography, time zone, language)

SAS Drug Development (SDD)

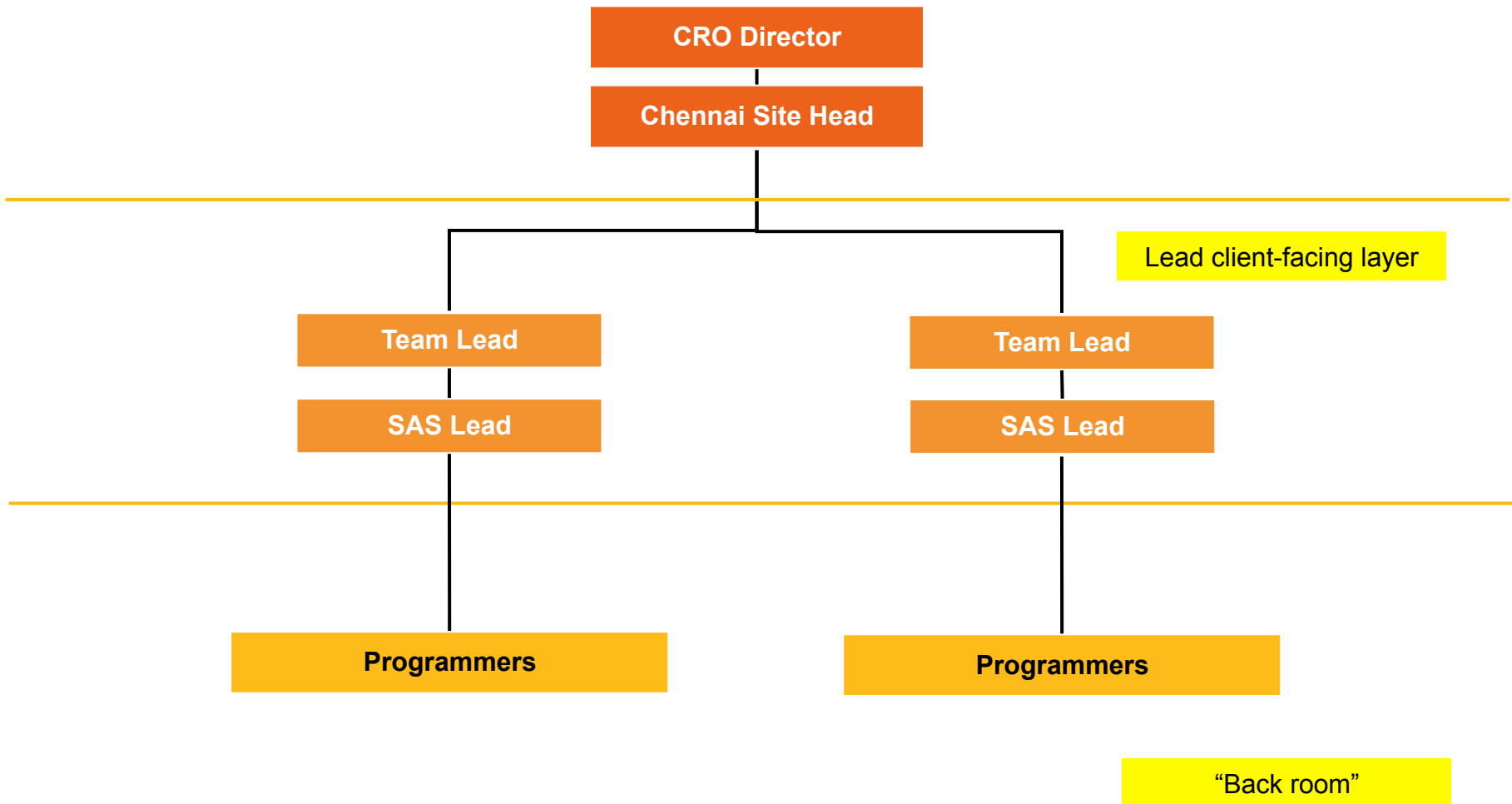
- Platform for centralized data repository and statistical computing environment
- 21 CFR Part 11 compliance
- Centrally hosted, validated and managed
- Functionality supporting technical and process control
- SDD is same technology increasingly adopted to enable clinical trials data sharing for external researchers as part of the industry-wide transparency movement



Establish team structures



CRO Team Structure



Role of NVx programmers / statisticians

■ Statisticians

- Work closely with the internal programmers to generate clear and complete communications to FSP staff on (a) programming requirements; (b) project priorities and timelines; (c) issue identification and/or resolution
- Participate in structured meetings and review/accept end products

■ Programmers

- Lead Programmer coordinates programming activities and monitors overall quality and compliance within project
- Work closely with the statisticians to understand and prioritize tasks
- Create/review programming specifications
- Oversight of FSP programming for a set of studies (timelines, quality, issue resolution)
- Understand and promote harmonization of process and practice within project area
- Programming of tasks allocated to internal programmers

Role of CRO programmers

■ Team leads

- Organize their teams, manage and track work assignments, communicate with NVx leads
- Responsible for timely delivery and quality
- Hands-on programming as needed

■ SAS leads

- Become technical expert with NVx system and process (“trainer” at CRO)
- Hands-on programming (particularly more complex tasks)
- Provide guidance to rest of team and ensure technical/process quality

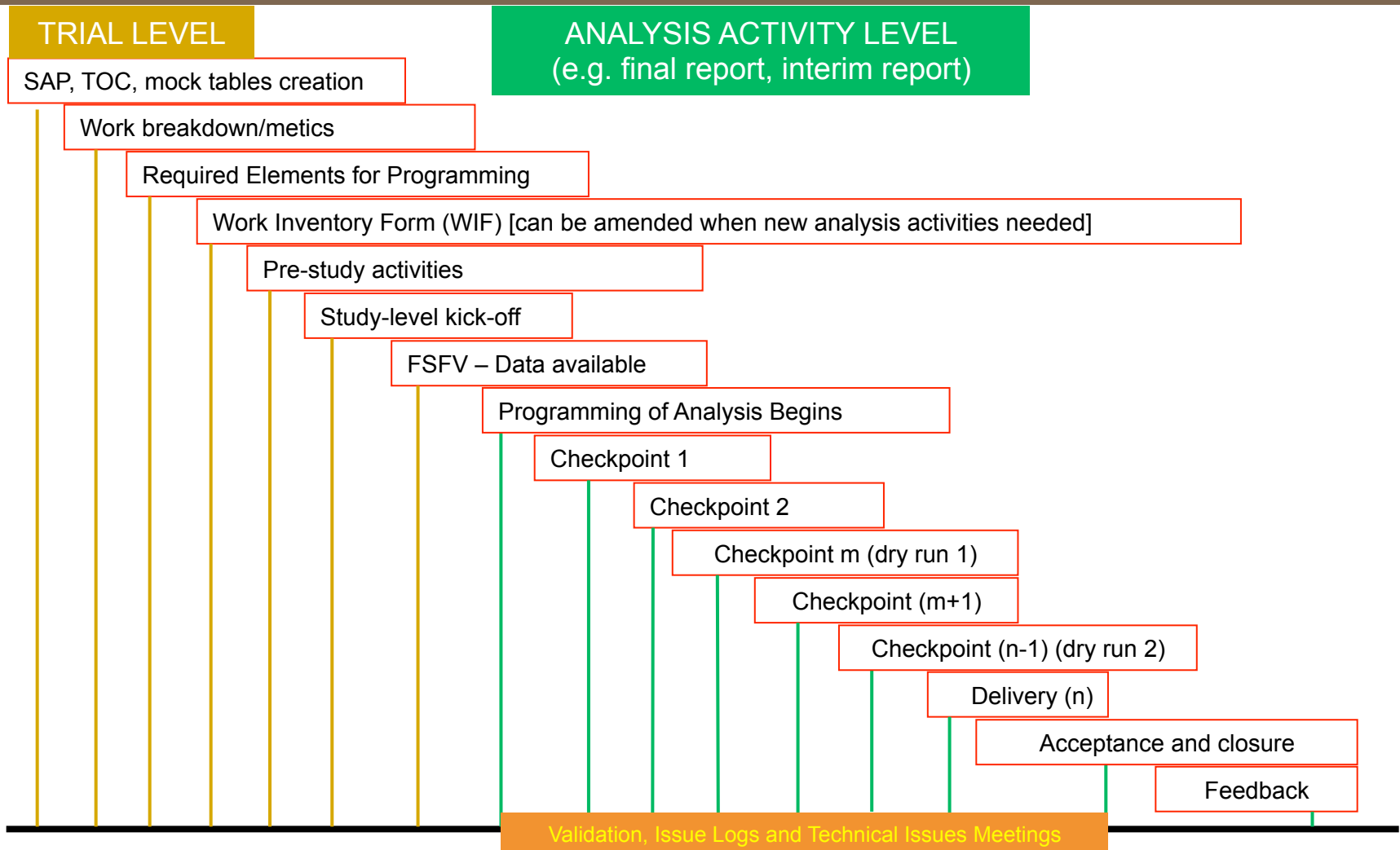
■ Programmers

- Execute assigned programming tasks
- First-line for quality

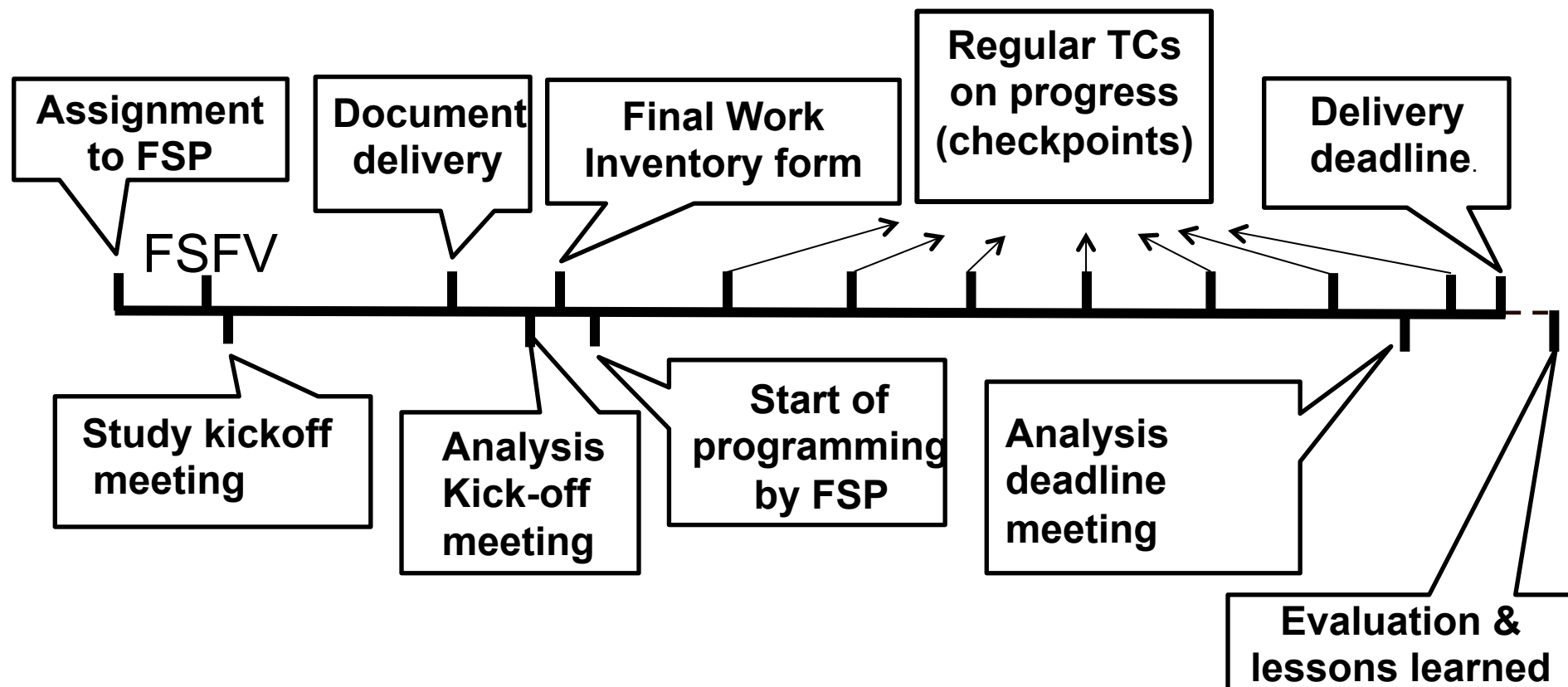
Delegation of analysis activities

Analysis Activity	Who
Clinical Study Report TFLs	FSP
Interim analyses	FSP
DSMB analyses and support	Case-by-case (NVx or outsource)
Ad-hoc (pre and post CSR)	NVx
Annual safety reports (DSUR)	FSP
Publications	NVx
Support for inspections	NVx
Pooled analyses	FSP
Submissions	NVx or outsource
CT.GOV or EURACT	FSP
Unusual patterns	FSP

Overall Timeline per analysis activity



Structured Workflow Timeline



Documentation and expectations

- Work inventory form (WIF)
 - A “contract” specifying tasks, pertinent documents, people, dates, deliverables, expected effort
- Programming specifications
 - Lists of TFLs, mock tables, technical details
- Issue logs
 - Capture key questions and answers
- “Quality loop”
 - Checklists prescribe the types of checks to do and what to look for
 - Validation documentation to comply with work procedures

Types of meetings

- Partnership-level meeting (monthly)
 - Agenda: Review project portfolio (priorities, timelines, status, deliverables, new studies, cancellations). Review personnel (joiners, leavers, skill sets, quality, holiday schedule, behaviors).
- Study-level kickoff (4 weeks before programming start)
 - Agenda: Review of study details provided in WIF. Agree on deliverables, timelines, and checkpoints
- Analysis-level checkpoints (regularly during programming)
 - Agenda: Review deliverables to date. Discuss issues and quality. Establish escalation path if needed.
- Technical issues meetings (as needed)
 - Agenda: Discuss specific issues encountered while working with NVx systems and processes

Miscellaneous

- Measuring performance and tying back to business
 - Metrics and Key Performance Indicators (KPI)
 - Unit costing
 - Replacing personnel
 - Developing a “bench”

- Disputes and conflicts
 - Escalation paths
 - Operational committee

- Cultural elements and travel
 - Establish criteria / opportunities for face-to-face interactions
 - Secure management buy-in and budget
 - Awareness of geographical culture elements and tie-in with work

Example KPIs

■ Timeline and deliverable based

- % of time when expected deliverables provided on-time with sufficient quality
- Number of tables requiring re-work post delivery / post checkpoint
- Number of days delay to provide deliverable
- Number of output delivered
- Number of errors determined during peer review

■ People and process based

- Number of questions regarding computing considerations and logic [purpose: measure of complexity, dirty data, unclear specs]
- Number of technical questions on standard software [purpose: measure user friendliness of std. reporting macros]
- Number of technical questions about process [purpose: measures clarity and logical consistency of SOP and WI]
- Number of technical questions about SDD [purpose: measure of ease of use of the system]

Implementation challenges

■ Meeting Expectations

- Time required to complete tasks
- Amount of people required to complete tasks
- Overall trust

■ Quality

- Compliant with process, but problems with content in the output
- Lack of awareness for across-output consistency

■ Required skill sets – need for development

- NVx: communications, project oversight skills
- FSP: analytical skills

Concepts Applied and Lessons Learned

- Communications are key
 - A conduit to establishing trust
- Management of stakeholders
 - Recognize stakeholders: internal programmers, statisticians, clinicians, QA, alliance
- Build key new skills
- Establish budget for face-to-face meetings
 - Travel can be incentive, facilitates “feeling part” of the team
- Document the working model somewhere (e.g. “service level agreement”)

Continuous improvement

- Observe, recognize problem points and tweak as needed
- **Example:** standard software is complex, relies on experienced people. Need to simplify system and enhance skill set
- **Example:** clear instructions to avoid ambiguity → consistency of good technical specs and mockups, bridging mental gap between SAP and programming
- **Example:** meet quality expectations → increased use of checklists, increased screen sharing and screenshots when interfacing

References

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Questions and Feedback



Contact

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