Evaluating and Improving the Efficiency of Your SOPs by Cross-Functional Mapping

Drug Lifecycle Tracking Application (DLTA)
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1

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Project Management Solution for the Pharmaceutical Professional

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2

SOPs Drive the Time and Cost of Tasks

- Each process may be covered by anywhere from 10 to 100+ SOPs
- Each SOP addresses one or few closely related tasks
- Each SOP may involve multiple personnel
- Each individual may need to follow 5-15 SOPs
- SOP training and compliance is expensive
- SOP non-compliance is mostly related to the sheer number of them to follow and the volume of tasks to remember

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3

Limitations of SOPs

- SOPs are mostly written as standalone instructions and distributed across multiple departments or offices.
- Individuals are trained on each SOP relevant to the tasks he/she performs, and are seldom trained on the cross-functional relationships that are critical to perform a group of tasks in sync.
- With a majority of the processes it is nearly impossible to see the holistic process view.

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4

Case Study: Clinical Trial Management

- **Large multi-site clinical trial**
  - About 70 sites, CRO team of about 30 personnel (clinical operations, safety monitoring, supplies, data management, regulatory affairs, admin.)
  - Along with site teams, more than 400 personnel to keep track of
  - About 130 SOPs to follow
  - Hundreds of new documents every month
- **Extensive time and money for managing projects**
  - One project meeting every week, about 10 ad hoc meetings, hundreds of "update" emails each week
  - About 50% of time spent tracking tasks, manually
  - MS Project and MS Excel were the basic technology
  - CTMS required extensive manual entries for output reports

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Case Study: The Issues

- **Timeline Delays**
  - Site initiation behind schedule
  - IND behind schedule, forgotten steps, missed time-lines
  - Supply chain unprepared
  - Projected start time from 3-6 months to 6-9 months
- **Cost Over-runs**
  - Project management fees
  - Supply management fees
  - Rush fees to catch up

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Case Study: The Solution - *Automation*

- **SOP Automation**
  - Map all processes with intra- and inter-linked descriptors
  - Assignment of roles/titles with each step of the process
  - Built automated online trackers for all team members
- **Integration and Training**
  - Team collaboration in stepwise integration starting with top program managers all the way to the admin staff
  - Gradual department-wise implementation starting with clinical operations
  - Expansion to pre-trail and post-trial tasks for future trials

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Maps of Individual SOPs

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8

6. Procedure: — Responsible Personnel

6.1 Assign a statistician/programmer to develop a computerized program for analysis or presentation of clinical trial data. — Department Head

6.2 Draft a computerized program (e.g., SAS, S, StatXact) after reviewing the table template, protocol, annotated CRF, data conventions, and other relevant materials (e.g., existing SAS macro archive, DO/BM binder, DM binder). Include the following elements: — Statistician/ Programmer

- 6.2.1 Program name
- 6.2.2 Program description
- 6.2.3 Name and location of SAS macros used in the program
- 6.2.4 Package version e.g., SAS 11.0, StatXact 3.1
- 6.2.5 Author
- 6.2.6 Date the program started. (assignment date)
- 6.2.7 Date of last modification
- 6.2.8 Description of the last modification

6.3 Execute the program using properly formatted data. — Statistician/ Programmer

6.4 Perform the following QC checks: — Statistician/ Programmer

- 6.4.1 Review the log and assure it is error free
- 6.4.2 Review the output
- 6.4.3 Assure that all program warnings are explainable
- 6.4.4 Review the Logic

6.5 Independent evaluator validates the program as follows: — Independent Evaluator

- 6.5.1 Confirm the results of 6.3 by using the same data and an alternative method of calculation such as different SAS PROC/other package/manual check
- 6.5.2 Review the program logic
- 6.5.3 Review the assumptions and the limitations of the

9

Cross-Functional Mapping of SOPs

Way to connect all SOP-driven tasks

- Using detailed process maps for each SOP
- Assign roles and time-lines to each step
- Find connectors and junctions
- Build multi-level SOP map: Level 1, 2, 3,..
  - Not more than 5 levels, if possible
- Build a platform technology to use the cross-functional maps

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10

SOP Automation Through Enterprise-Level Work Management Approach

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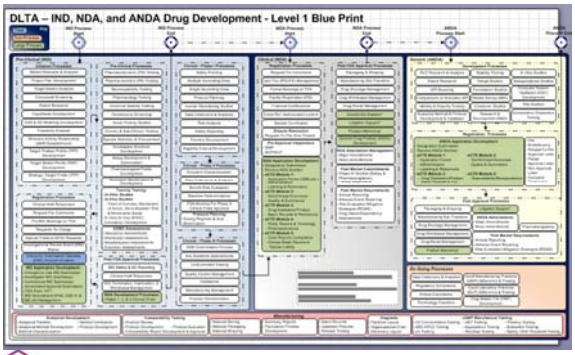
11

Level 1: Holistic View of the Entire Organization



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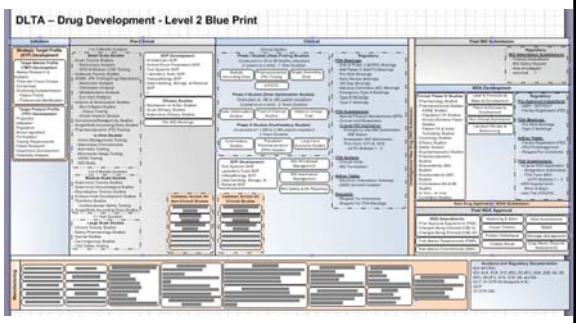
12

Level 2: Department Level Organization



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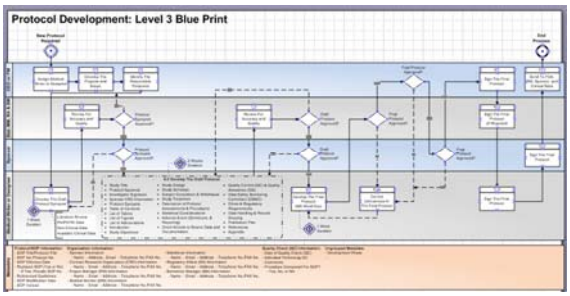
13

Level 3: Group Level Organization



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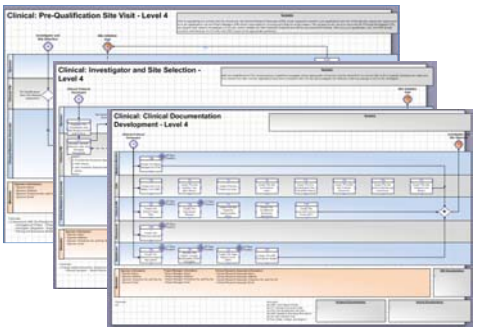
14

Level 4: SOP Level Organization



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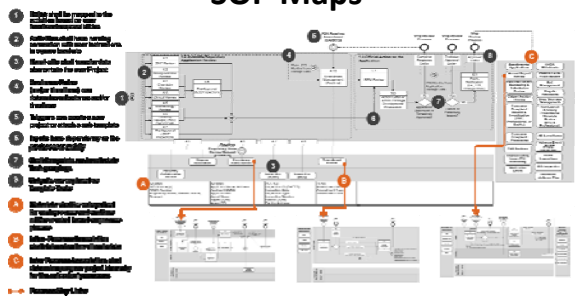
15

Best Practices for Cross-Functional SOP Maps



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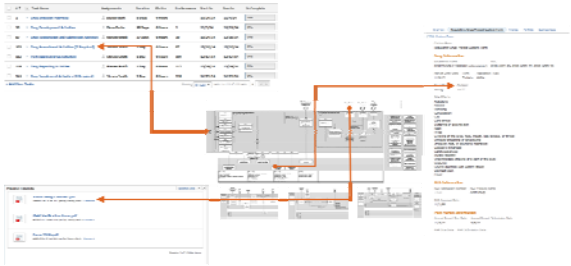

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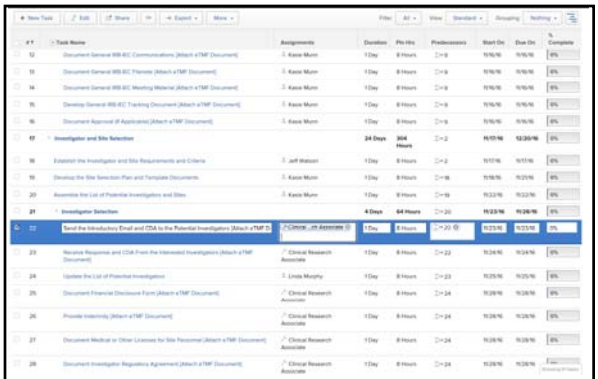

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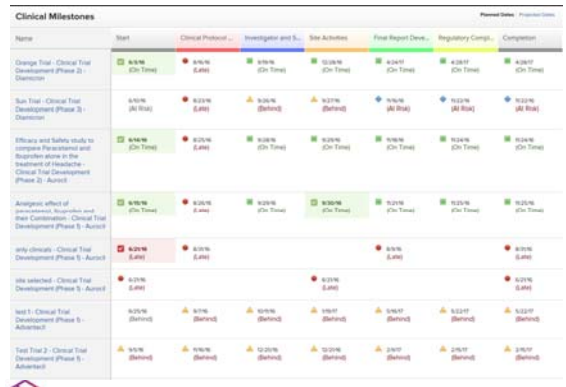

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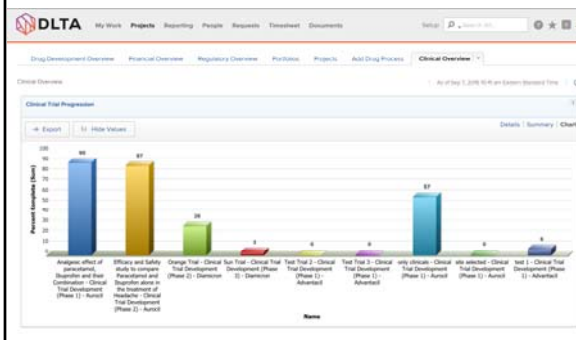

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- Ease strategic planning of projects
  - Pre-built task maps covers almost all areas of development, roles and time assignments
- Dynamic work-flow management
- Transparent performance matrices
- Team motivation via recognition
- Easy set-up, short training, quick adaptation

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Dynamic Work-Flow Management

- Adds ability to work together dynamically
- Centralized transparent team communication
- Plan and execute at the same place leads to real-time fluid planning
- Real-time task tracking and accountability
- Reduces project management costs by time-saving on meetings and gets rid of painfully long email threads

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22

Transparent Performance Matrices

- Each task assigned to a “job role”
- Roles are customizable and can be linked to job titles, job responsibilities, and training
- Real time performance (quality and time) tracking for each team member
- Who's responsible for what gives people incredible recognition and accountability for their work

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23

Key Benefits

1. Reduces guess work by automating your SOPs helping your team with completing and reporting work on time
2. Single place to manage high and low level projects together
3. Visual synchronization of high and low level tasks gives the ability to set priorities for managers
4. Rapid project launch
   - Less than weeks for planning needed
   - Accurate cost and time projections
   - Accurate resource and personnel allocation

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24

Thank You!

Questions and Comments

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