CluePoints

Data-Driven, Risk Based Approach to Monitoring

Vertex

21st July 2025

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Agenda 21st July

1. Overview of Key Use Cases for Adaptive Site Monitoring

SDR Sampling, Data Driven Monitoring, TSDV.

2. Deep Dive into SDR Sampling

Overview of the process, what data is needed, KRI configuration, demo, time to go-live, future roadmap.

3. Deep Dive into Data Driven Monitoring

Overview of the process, what data is needed, algorithm configuration, demo, time to go-live.

4. Q&A and Next Steps

Key Questions from Vertex

- **Objective**: reduce/increase SDR based on site risk.

- **Key Questions**: How CluePoints current users are using CMP/SPOT to:

    1. Perform targeted review, at monitoring visits, based on outputs from CluePoints,

    2. Understand what needs to go into the system (duration of time that will take, etc) in order to accomplish #1,

    3. Really get a feel for how this system has changed their monitoring strategy and if they have quality indicators/review that shows consistent output with reduced footprint.

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Overview of Use Cases for Data Driven Monitoring

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Data-Driven, Risk Based Approach to Monitoring

	SDR Sampling	Data Driven Monitoring (Site Visits)	Targeted SDV
What	Dynamically adjust the SDR sampling strategy for each site based on site risk.	Transform the traditional fixed and scheduled monitoring approach to a data-driven decisions model, based on the workload estimation and risk evaluation.	Dynamically adjust SDV for each site based on site risk.
Technology Today	CMP (KRIs) + Manual Process outside of CP	CMP + SPOT	
RoadMap	CMP + SPOT Integration with Veeva CTMS	Integration with Veeva CTMS	CMP + SPOT Integration: RAVE EDC
Customer Use Case	astellas	sanofi	sanofi

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SDR Sampling Use Case

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SDR Sampling

- Overview of the process,
- What data is needed,
- KRI configuration,
- Demo,
- Time to go-live,
- Future roadmap.

Dynamic SDR Sampling

- Goal: To dynamically adjust the SDR sampling strategy for each site based on site risk.

  - Assess the site quality by assigning a global score to each site having at least one patient entered into EDC.
  - For each metric: a low, medium or high risk is assigned to each site in the CMP.
  - CMP derives automatically the site score based on the value assigned to each risk and the weight of each metric.

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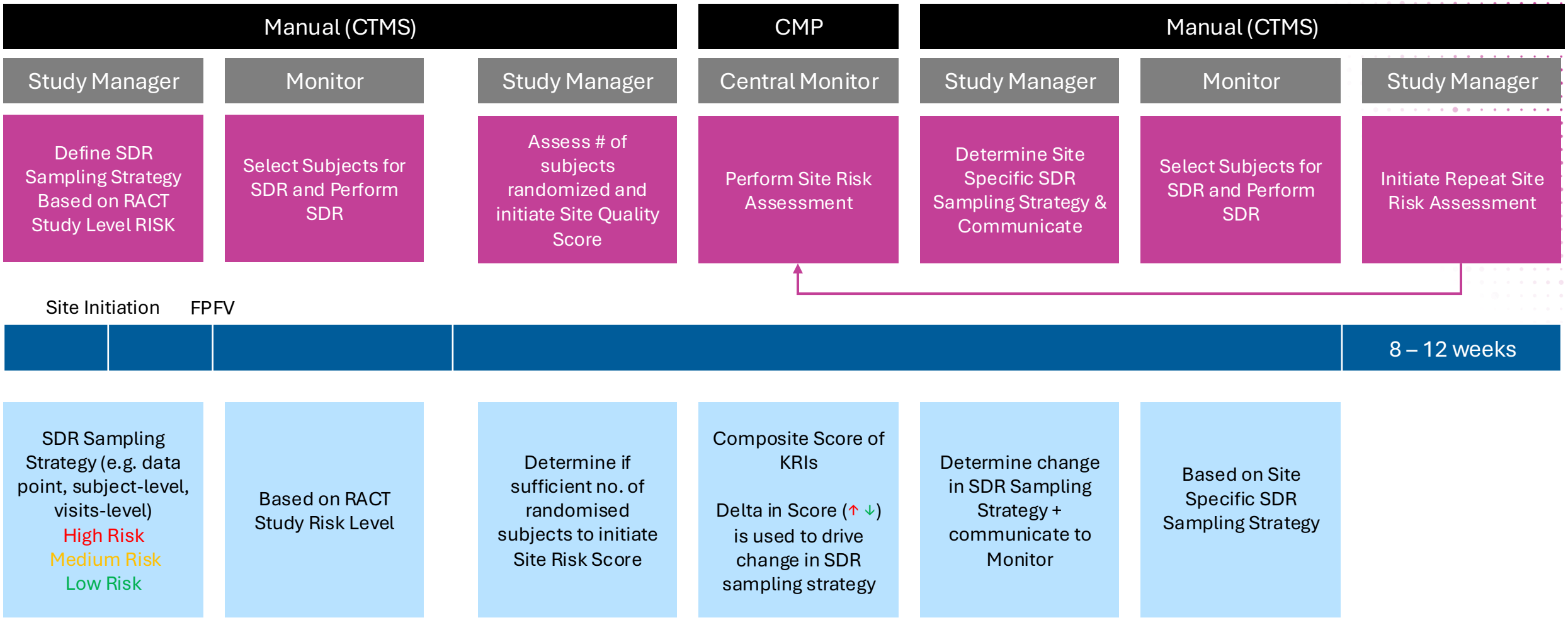
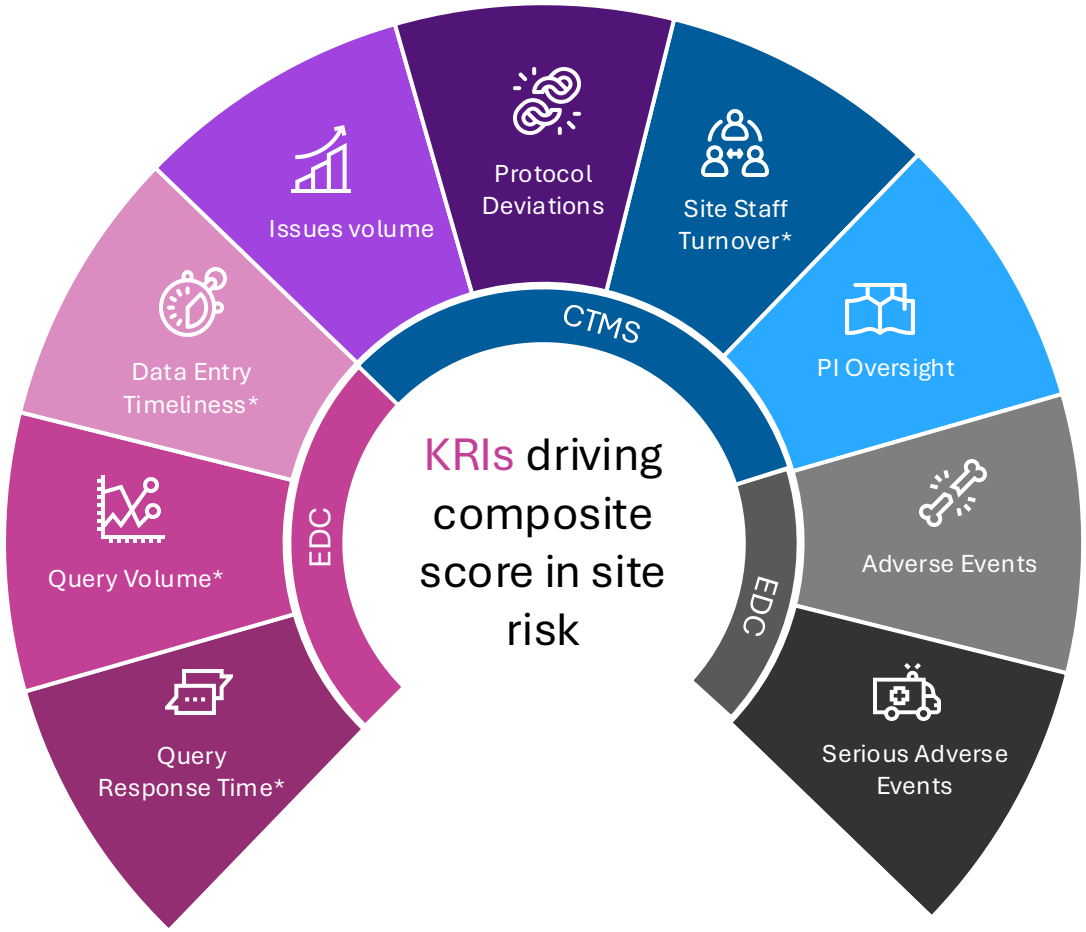
SDR Sampling: Digitising The Process



Example KRIs Determining SDR Sampling Strategy

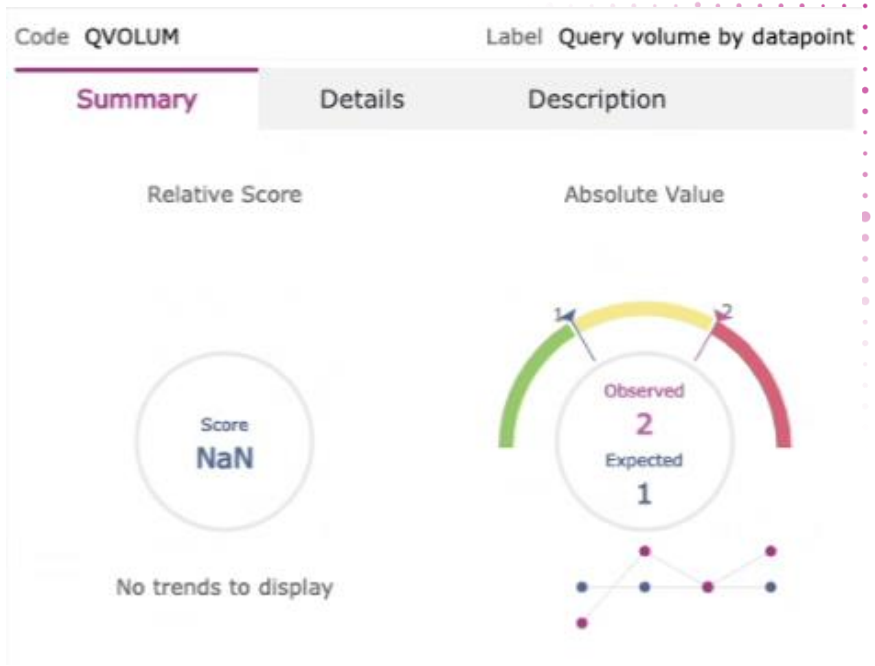


Calculate Risk for Each KRI Metric

0 = low risk

1 = medium risk is identified

2 = high risk



* Incremental

Example KRI

Metric: Query volume

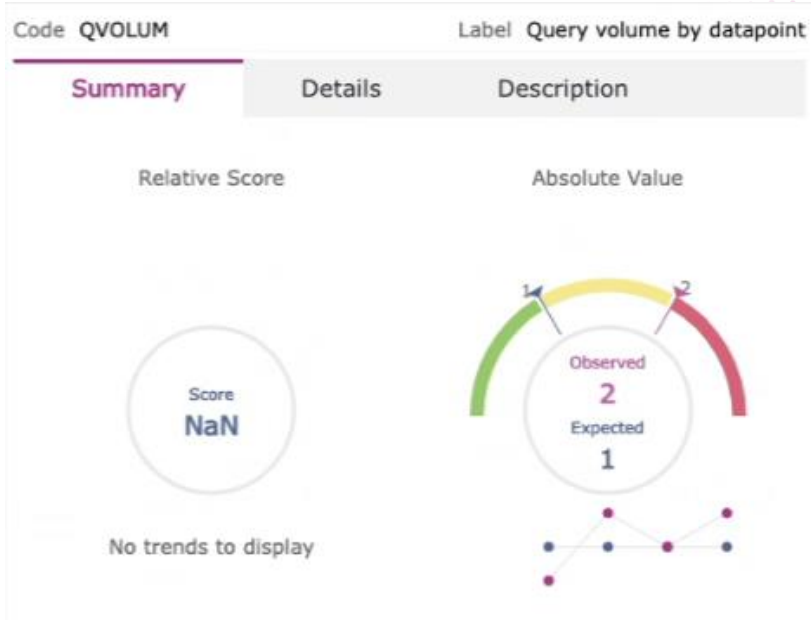
Definition: Rate of queries generated by datapoint for the site compared to the overall study data.

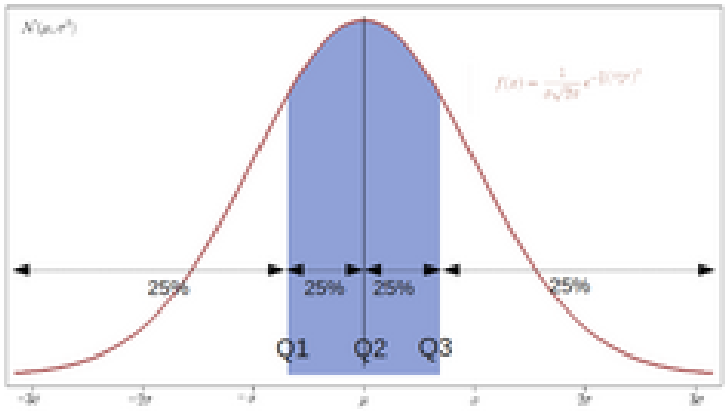
Risk Levels:

Risk Level	Thresholds	Risk Score
Low Risk	<= Q1 (0-25%)	0
Medium Risk	>Q1; <=Q3 (26-75%)	1
High Risk	>Q3 (>75%)	2

Notes:

- Keep only the datapoints (and corresponding queries) entered during the period of interest (the default period of interest is 6 months prior to the snapshot date).





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CMP Site Risk Demo

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Demo Agenda

- Configuration of KRIs
- Review of KRIs – KRI dashboard and example KRIs
- Review of global score, change in score, what is contributing to the change, trending of change (getting better / worse)

Typical Study Timelines (post go live)

Kick Off Meeting
- Overview of project
- Review operational process
- Define roles & responsibilities

Analytic Services Specifications
- CluePoints provides draft specifications
- Collaborative specifications review meeting(s)
- Client team approves

CMP Training
- Navigation
- Effective signal review and action management

Debrief
- Mitigation Overview
- Client Feedback

Kick Off Meeting	Data Transfer	Specifications	Signal Management Training	Risk Review Prep	Risk Review	Mitigation Review	Refresh or Close

Data Upload to CluePoints
- Starts the timeline
- Data transfer can occur prior to KOM

Signal Management Training
- Risk signal creation, investigation, and mitigation
- Actions creation and workflow

Review Signals
- Assess Root Cause
- Identify Follow-Up

Refresh or Close
- Archive if complete
- Plan next refresh

20 – 30 business days from Data Transfer (all data) to Risk Review

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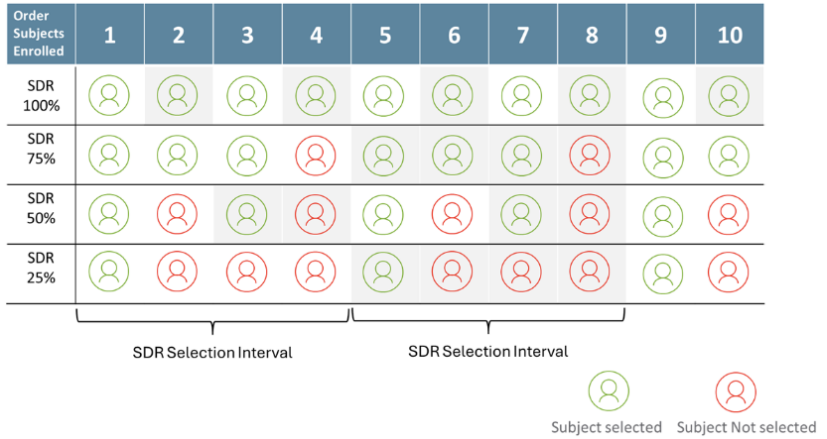
Future Roadmap

- SPOT Workflow
  - Action engine and decision workflows to document the decision-making process and trigger in change in SDR Sampling in CTMS.

- Veeva Integration
  - Integration (CluePoints API and Veeva CTMS API) to automate the change in SDR Sampling in Veeva CTMS.



https://veevaconnect.com/communities/ALLMDFMbEAA/content/BR5HF_gvUAA

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Data Driven Monitoring Use Case

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Data Driven Monitoring

- Overview of the process,
- What data is needed,
- Algorithm configuration,
- Demo,
- Time to go-live.

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Use Case 1: adaptive data driven decisions

Objectives

- Transform the traditional fixed and scheduled monitoring approach to a data-driven decisions model, based on the workload estimation and risk evaluation.

- Deliver a centralized approach to planning and adapting the scheduling of Monitoring visits.

Value

- Increase MV productivity (on-site vs. remote, frequency).
- Improve MV quality (compliance with the plan and consistent approach).

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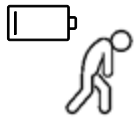
Why SPOT

Improve MV Productivity
Reduce monitoring costs through data driven dynamic monitoring – focusing resources where they are needed most

Reduce Travel and Expenses Costs
Reduce travel costs through increased use of remote visits

Support Achievement of Environmental Sustainability Goals
Reduce carbon footprint and achieve a net-zero environmental impact

Ratio of on-site : off site MV Frequency: interval between MVs On-site days/Patient/Year



Reduce CRA Burnout and Improve Employee Wellbeing
Through more efficient workflows for CRA, reduce burnout, turnover and impact and on management Reduced unnecessary travel

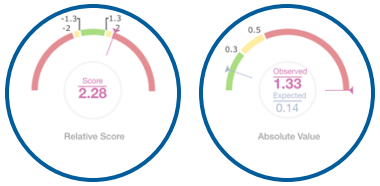
Reduce CRA turnover over (past 12M)

Improve MV Quality
Consistent approach to preparing and executing MV Align activities with each site's specific needs and risks - focus on what matters

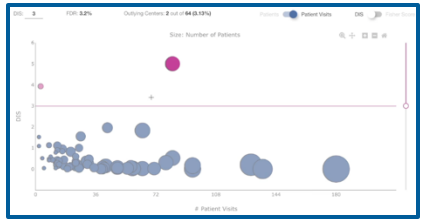
SPOT workflow

Input Data

KRIs



DQA



Clinical Data

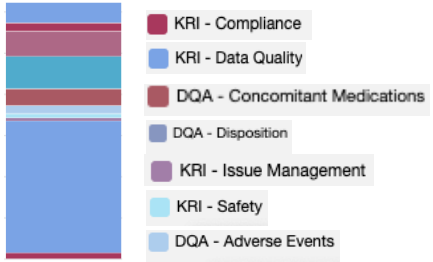
New & number of AE/SAEs,
Number of queries, …

Operation Data (CTMS)

MV Plan, Enrollment, Milestones, IMP, SDR & SDV
to be done, new ICF, …

Data Derivation

Site Level Risk Score Calculation

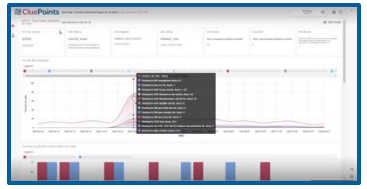


Workload estimation (backlog, new & predict)

Review Dashboards

Country level dashboard

Site level dashboard



Document & Take Action

Adjust Monitoring Activities

Reason & Rational

Plan/Modify MV Date

Create a new MV
Update the date of the MV

Modify MV Type

Change type (on site vs. remote),

CTMS

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Demo DDM

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Demo Agenda

- Country Level and Site Level Review (Risk and Workload)
- Drill down to a site - review what is driving risk and workload
- Review actions
- Log of decision and actions

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Four areas to prepare in parallel to study level implementation planning

Data Integrations

Data sources:
Configurations:
Outbound integrations:

Process and Policy

Need to update SOPs? To look at
Any update to work instructions / job-aids:
Review WI/J-As / functional plans for update / adjust existing processes. Process optimization for realizing efficiencies

People and Organization

Stakeholder Alignment: (executive alignment, functional groups impact, end user engagement)
Resource Availability: Implementation resourcing

Governance and Compliance

Any other compliance requirements:
Vendor / CRO contracts review?

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Workload Algorithm – CluePoints Template

Activity	On Site (hours)	Off Site (hours)	Input Data Sets
New AE leading to treatment discontinuation	0.33		EDC.AE, EDC.DS
Open Issues	0.075	0.175	CTMS
New site staff		2	CTMS
Protocol amendment		1	CTMS
Other tasks (patients being in run-in or pre-screen visit)		0.25	EDC.visit
Open Deviations	0.075	0.175	CTMS
Screening visits	1.5		EDC.visit
Eligibility visits (Day1)	0.75		EDC.visit
Standard visits (other visits)	0.5		EDC.visit
ISF	3		CTMS
ICF review	0.33		EDC.DS
IMP visits	0.16		EDC.exposure
Lab visits	0.33		EDC.lab

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Risk Algorithm – CluePoints Central Monitoring

Signal	Weight	Comment
Signal with open status	1	Mitigation is Open
Signal with a high priority	1	Signal having the priority 'High'
Open signal with a low priority	0.2	Signal having the priority 'Low'
Signal updated in the last 3 months	1	Number of days since last mitigation until the day of algorithm execution
KRI Safety	5	Signal written on the KRI safety (AE rate, SAE/AESI rate)
KRI Data Quality	1	Signal written on the KRI Data quality (Query Cycle time, Missing visit, out of window visit rate, eCRF visit to entry cycle time)
KRI Enrollment and Retention	3	Signal written on the KRI on Lost to FU, premature treatment discontinuation
KRI Issue Management	4	Signal written on the KRI on Protocol deviation
DQA Adverse Events	1	Signal written including any AE data (domain of data = Adverse event)
DQA Concomitant medication	1	Signal written including any Con Med data (domain of data = Concomitant medication)
Signal with critical data	1.5	Critical data flagged in the set-up
….		

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Risk Algorithm – Non-CMP Metrics Examples

Signal	Weight	Data Source
Query Response Time (Previous 6 months)	1	EDC (query)
Query Volume	1	EDC (query and audit trail)
Data Entry Timeliness	0.2	EDC (visit and audit trail)
Study Staff Turnover	1	CTMS
PI Oversight	1	CTMS
SAE Rate	1	EDC
AE Rate	0.75	EDC
Screen Failure Rate	0.5	IRT
Protocol Deviation Rate (IMPORTANT)	1	CTMS
Protocol Deviation Rate (Non IMPORTANT)	0.25	CTMS
Other Deviation Rate (Issues that matter)	1	CTMS
Other Deviation Rate (Issues)	0.25	CTMS

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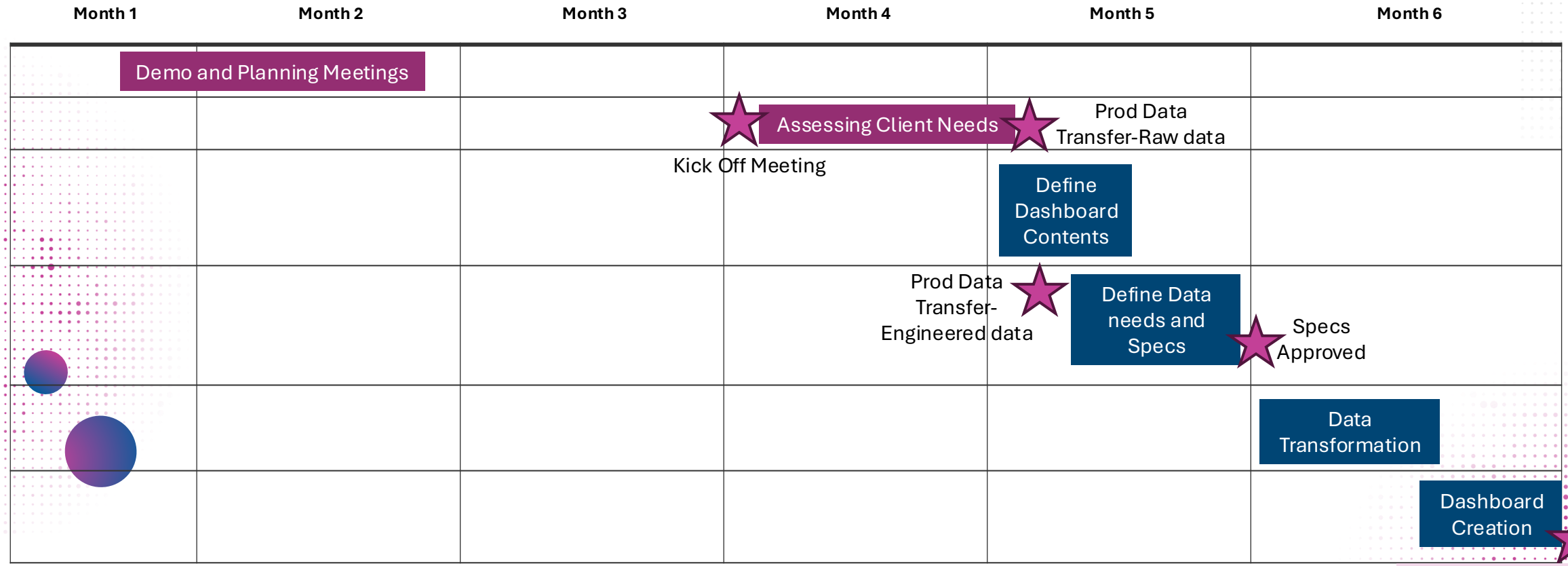
Overall Process

- Phase 1: Assessment Phase
- Phase 2: Initial Implementation
- Phase 3: Finalize Implementation
- Phase 4: Scale-up Phase

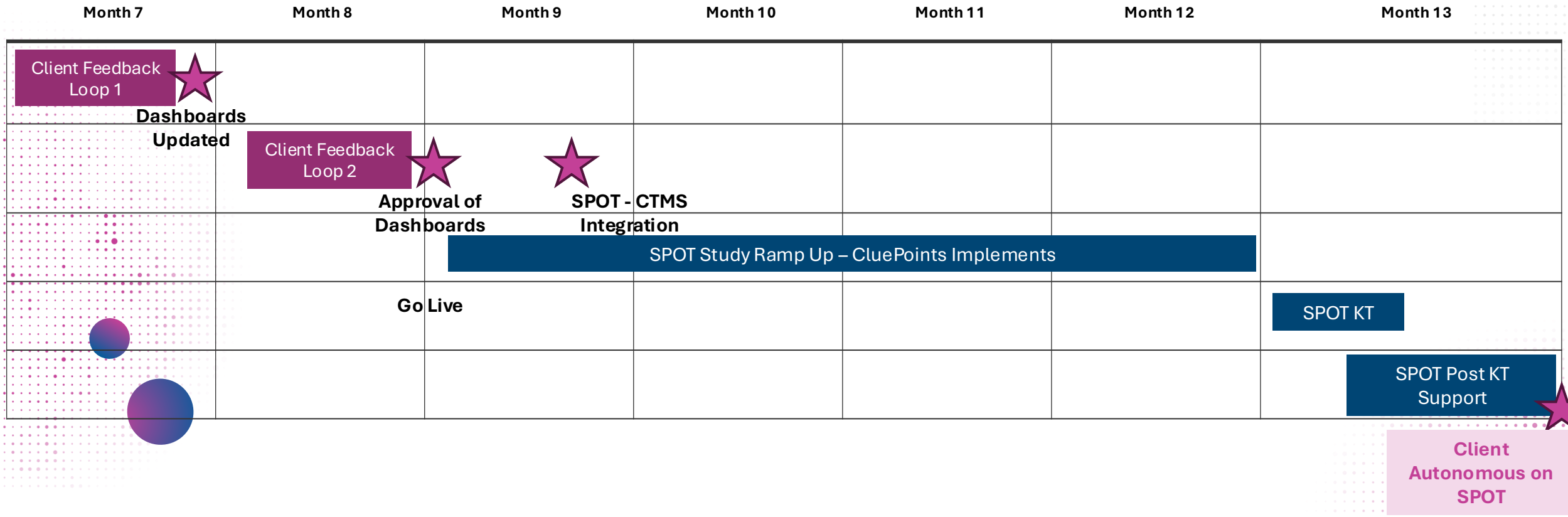
Timelines

Kick Off/Assessment & Initial Implementation Phase



Timelines

Finalize Implementation & Scale Up Phase



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SPOT Dashboards - Primary Implementation versus Refresh

Activity	Implementation	Refresh
Understand the algorithm	X	
Align on data transfer and specifications	X	
Determine which activities and measures will contribute to the workload and risk computation	X	
Upload data and sync data	X	X
Determine the weight of each activity	X	(X)
Derive and transform any needed data for the algorithm	X	
Configure the configuration files and execute the algorithms	X	
Test the results of the workload and risk	X	
Create the dashboards	X	
Create the action templates	X	
Refresh dashboards		X

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Next Steps

1. Stakeholder Alignment
2. Data integrations and specification for workload / risk
3. Process optimization, changes to WIs,
4. Compliance and vendor conversations
5. Study selection, study implementation process, identify additional changes

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Thank You!