

Outsourcing of data validation activities:

How we set up the new collaboration with a CRO

10 November 2015 - DMB

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CONTEXT

Subcontracting of data validation since 2008 (DIRECT LINK)

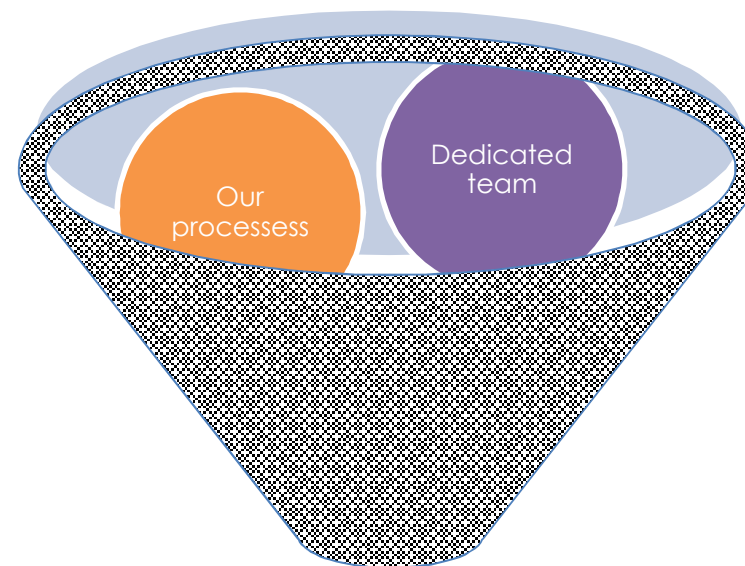
DATA VALIDATION

- *Review of query before sending
- *Review of investigator's answers
- *Validation of protocol deviations

→ On line process

DIRECT LINK

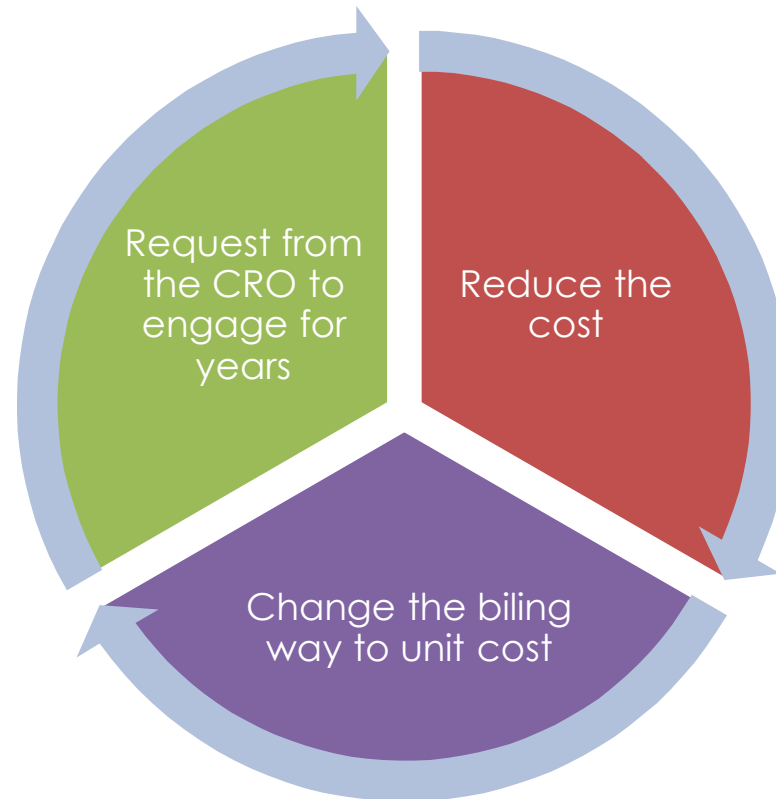
- *Direct access to SERVIER database
- *SERVIER tools
- *SERVIER procedures



Good quality

Outsourcing of data validation activities

In 2014: Need to change our DIRECT LINK CRO...



The challenges

Processes

- Processes review
- Trainings
- Communication

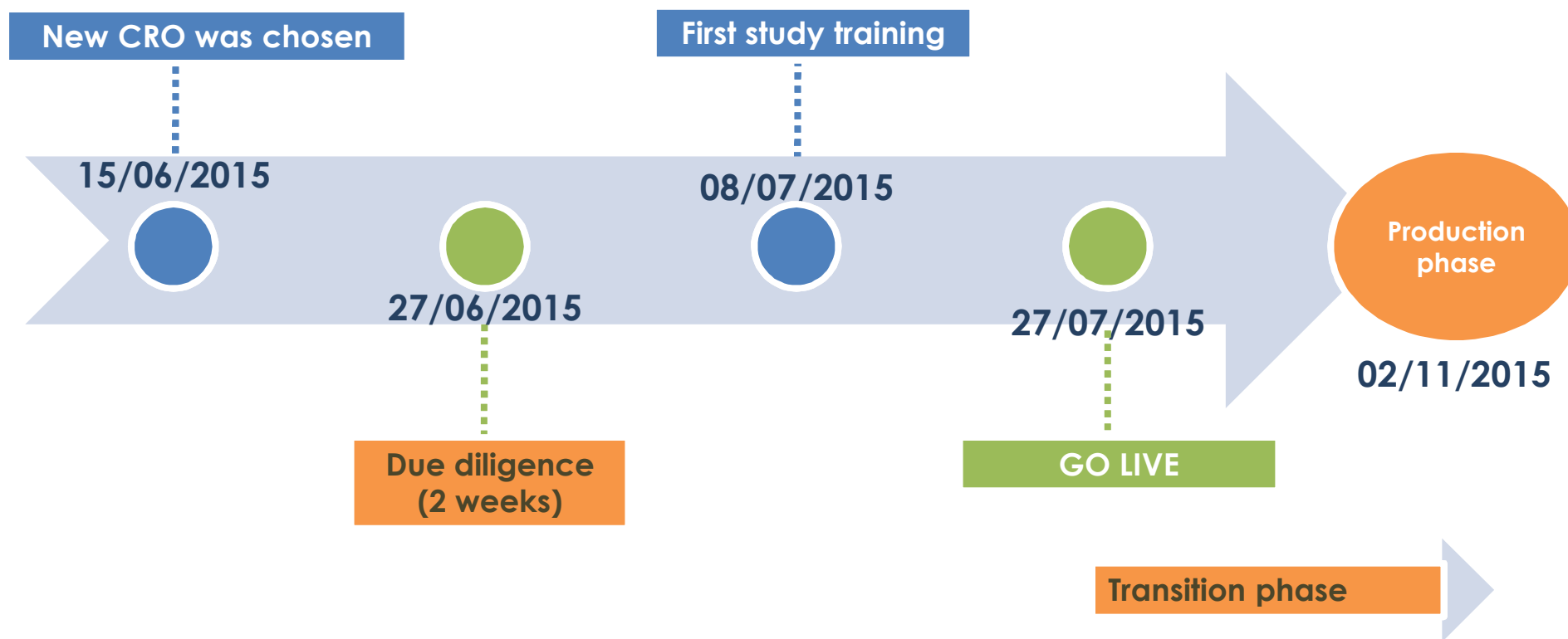


Business

- Unit definition
- Forecast
- Metrics



The story...



Processes



Query & deviation management

- Procedures
- Process map



Training process

- Global training plan
- elearning



Study transfer process

- Study transfer checklist
- Study kick off template
- Clarification log template



Communication

- Shared area
- Partner referent
- Communication plan



SERVIER partner referent is responsible to follow the process compliance

BUSINESS



Billing



Forecast



Indicators/Metrics

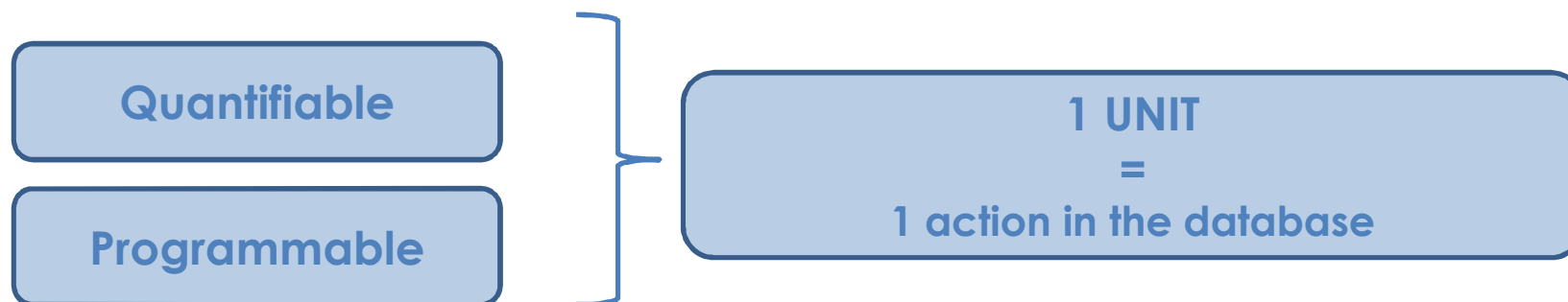


Communication

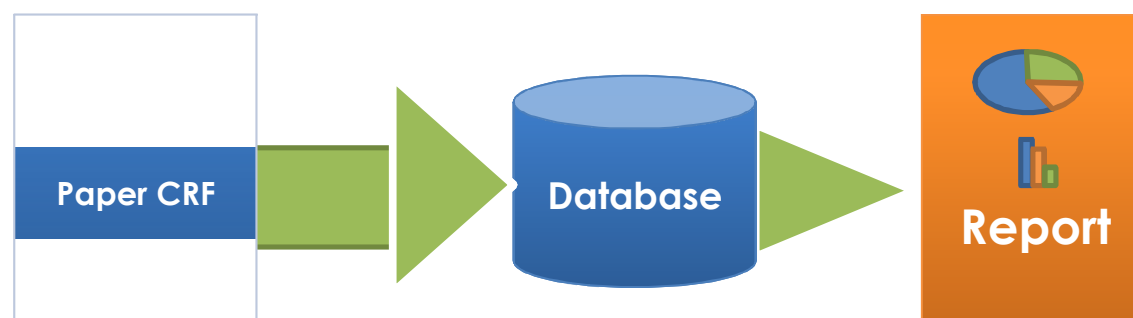


BILLING

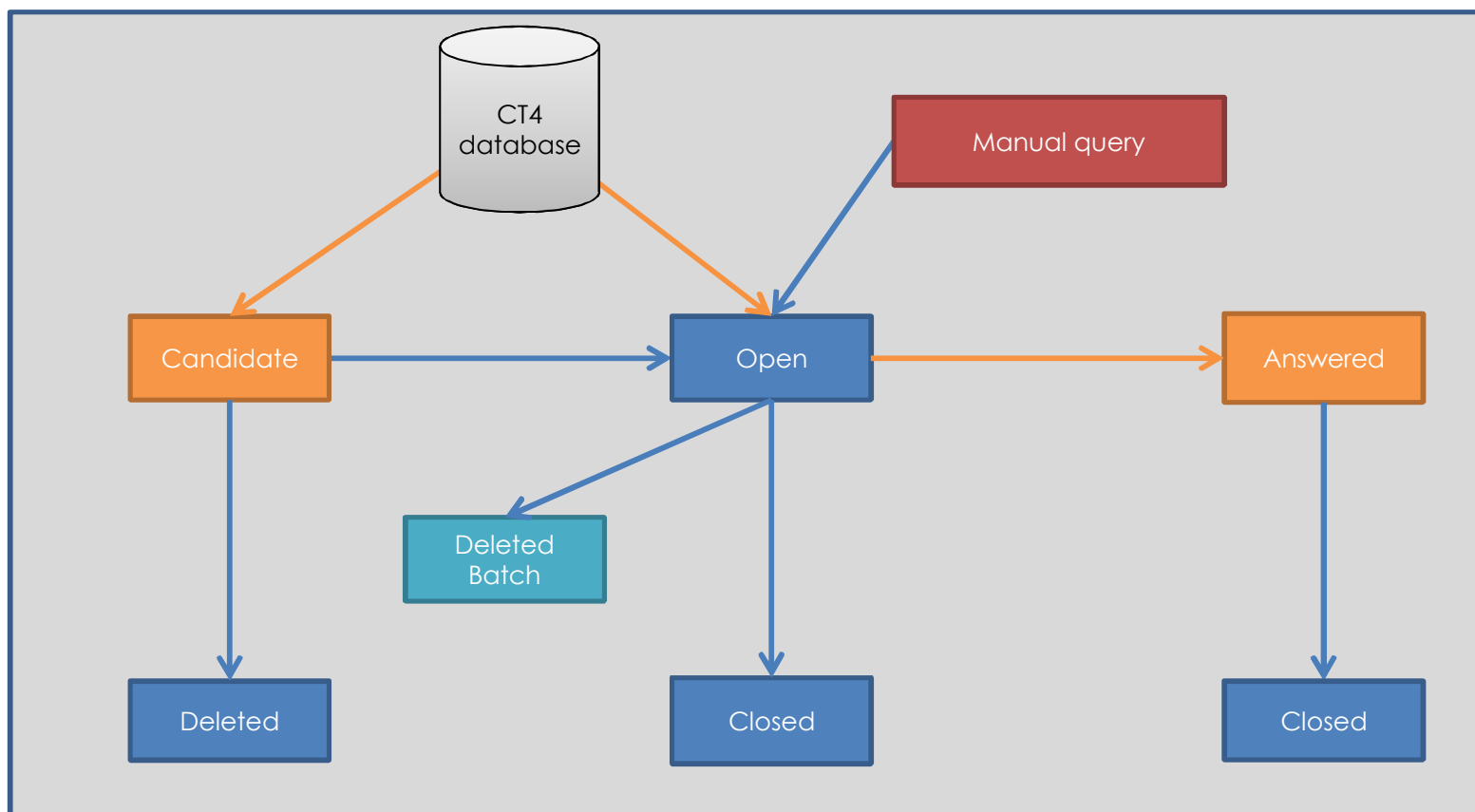
BILLING



‘Easy way’ to retrieve the information related to billing in the database



eCRF status / Queries



- CRO DM action not take into account (manual query, AC=autoclosed)
- CRO DM action take into account (open, closed, deleted)
- Inform system status change not take into account

Specific billing for the deleted Batch identify in ecrf with reason « DELETED BATCH x »

BILLING: Automatic reports

1. Report **programmed** by SERVIER

2. Program **validated** by the CRO

Each month, **SERVIER partner referent** runs the report and sent it to the CRO
The CRO provides the billing based on these figures.

Work for billing validation is reduced for SERVIER



Data From 28-8-2015 to 27-9-2015

1- Data Validation

Number of iteration managed by Cognizant DM	Iteration
NB OF QUERIES (e-crf queries)	7310
NB OF CT4 QUERIES (paper/dm CRF discrepancies)	309
NB OF CT4 QUERIES (centralized data discrepancies)	12
NB OF DEVIATION (protocol deviation)	1753
TOTAL NB OF ITERATION	9384

Data From 28-8-2015 to 27-9-2015

Obs	PROTOCOL	NB OF QUERIES (e-crf queries)	NB OF CT4 QUERIES (paper/dm CRF discrepancies)	NB OF CT4 QUERIES (centralized data discrepancies)	NB OF DEVIATION (protocol deviation)	TOTAL
1	CL149078001	16	3	2	0	21
2	CL149078002	1	0	0	0	1
3	CL155748002	61	0	0	12	73
4	CL180881005	2	0	0	0	2
5	CL306790010	7226	306	10	1741	9285
6	CL378989019	2	0	0	0	2



FORECAST



Reference database

- **Ongoing** reference
- **Based on 115 studies**
- Reference by axis, by phase, by type of data

Therapeutic axis	Phase	eCRF queries/visit	Deviations/visit
Cardiovascular	III	3,25	2,32
Neuropsychiatry	II	3,44	1,64
Cardiovascular	PKH	8,39	4,39
All	Central lab	0,75	-

- Reference by study:

PROTOCOL	STUDY DRUG	AXE	PAPER OR ECRF STUDY	NB OF PATIENTS	NB OF INCLUDED PATIENT	NB OF VISIT/ CYCLE	NB OF ITERATION (Queries, Discrepancies, Deviation) MANAGED BY DM	NB OF QUERIES (e-crf queries) MANAGED BY DM (iteration)	NB OF QUERIES (e-crf queries) OPEN BY DM (iteration)	NB OF CT4 QUERIES (paper CRF discrepancies) MANAGED BY DM (iteration)	NB OF CT4 QUERIES (paper CRF discrepancies) SENT BY DM (iteration)	NB OF CT4 QUERIES (centralized data discrepancies) MANAGED BY DM (iteration)	NB OF CT4 QUERIES (centralized data discrepancies) SENT BY DM (iteration)	NB OF CT4 QUERIES (centralized lab data discrepancies) MANAGED BY DM (iteration)	NB OF CT4 QUERIES (centralized IRS data discrepancies) MANAGED BY DM (iteration)	NB OF CT4 QUERIES (centralized data review discrepancies) MANAGED BY DM (iteration)	NB OF CT4 QUERIES (centralized other data discrepancies) MANAGED BY DM (iteration)	NB OF DEVIATION (protocol deviation) MANAGED BY DM (iteration)
CL112345001	S12345	CANCERO	ECRF	132	104	644	13697	4446	1392	1991	25	6238	1035	0	0	528	5710	1022
CL1412345002	S12345	CANCERO	ECRF	13	12	60	1333	704	223	91	0	205	58	0	0	0	205	333
CL178945001	S78945	CANCERO	ECRF	25	20	119	3639	1078	429	848	0	1030	49	0	0	285	745	683

Annual Forecast

Number of iteration planned for the year

→ Allow the CRO to validate capacity planning

- Reference
- Planned list of studies

Quarterly Forecast = work order

Number of iteration by study

→ based on the real information on studies

- Reference
- Real figures for the previous 3 months
- Algorithm: Product/TA, Study Protocol, Recruitment Curve

Coordination by the SERVIER partner referent



Indicators/Metrics

CRO oversight

Performance and quality

- Alert Servier DM weekly to follow validation activities by studies
- Discuss issues with CRO

Budget indicators

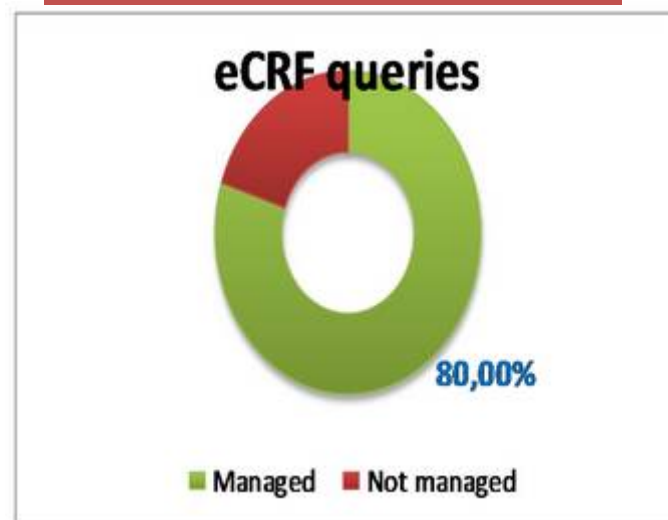
- Follow Year Budget, Quarter Budget, global budget

Coordination by the SERVIER partner referent

Performance indicators

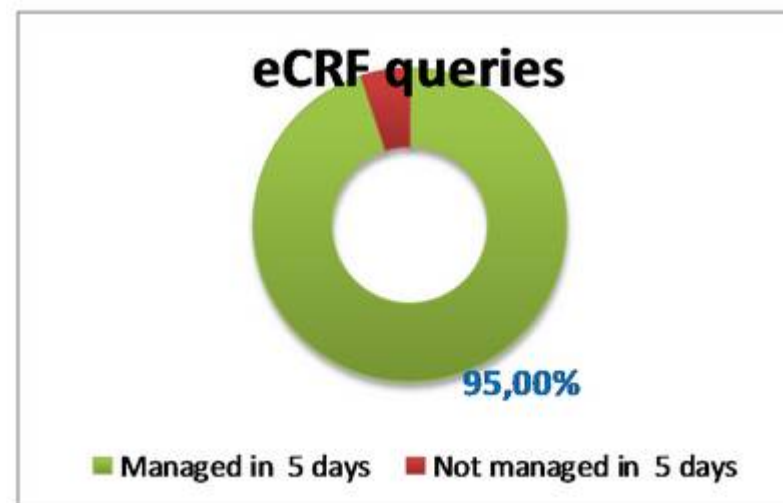
Queries management

MANAGEMENT



Delay


TIME TO VALIDATE



Specific process to identify queries waiting for programming correction.

SERVIER quality control done for each study every 6 weeks (frequency adapted to the study) on 10 % of iteration managed

Quality indicators

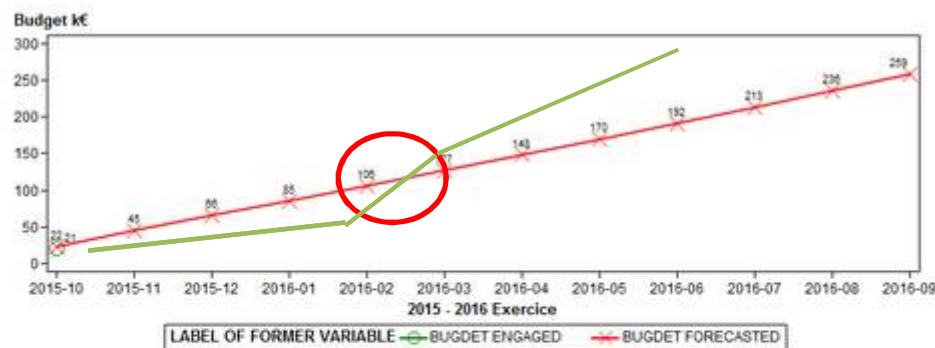
Number of control batch validated 12	Number of control batch not validated 1
Number of CRO questions 23	Qualitative assesement of CRO questions 

Performance indicator for the SERVIER DM on the time to answer CRO questions

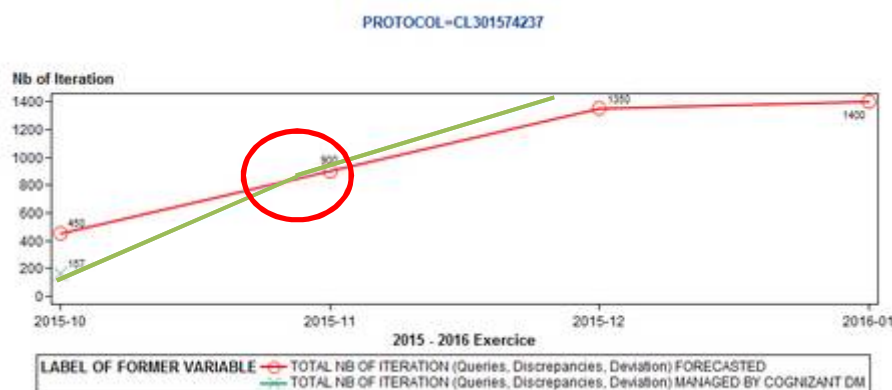
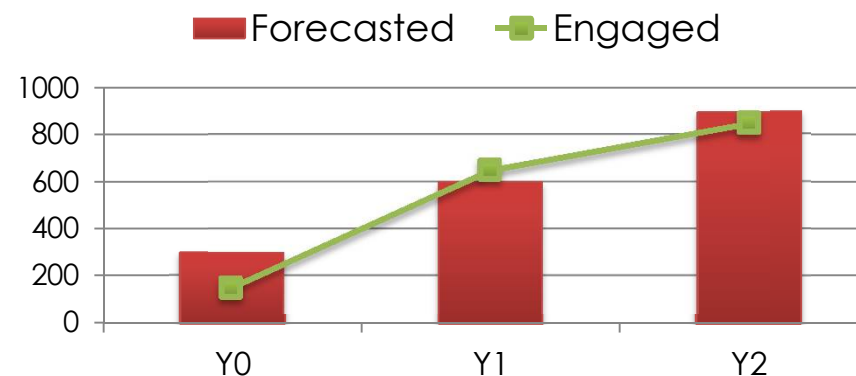
If Abnormality rate > 2 %
→ Action plan (training...)

Budget oversight

Budget indicators



	Exercice											
	2015-10	2015-11	2015-12	2016-01	2016-02	2016-03	2016-04	2016-05	2016-06	2016-07	2016-08	2016-09
	k€	k€	k€	k€	k€	k€	k€	k€	k€	k€	k€	k€
BUGDET ENGAGED	20.88											
BUGDET FORECASTED	22.37	44.78	65.54	85.27	105.90	127.18	148.38	169.58	191.60	213.33	236.42	259.05



Follow up: Forecasted compare to Engaged

Alert: when Engaged budget is under or above Forecasted Budget (+/-10%)



COMMUNICATION



Study ad hoc meeting

Topic:

- Study planning
- Study clarification
- Re-training

Participant:

- SERVIER DM
- CRO DM

Follow up meeting Every week (1h30)

Topic:

- Governance
- Follow CRO activities
- Improve process
- Resolve general issues
- Priority management

Participant:

- SERVIER partner referent
- CRO partner referent

Operational Steering committee

Topic:

- Engagement start up status
- Transition status
- Training status
- Pilot phase status
- Study Quality
- Key challenges

CONCLUSION

First experience with a CRO based in India

We work to built a strong partnership based on transparency and confidence

Opportunity to challenge our processes et create the reference database

Next steps...

- Validate our forecast**
- Be able to justify differences in buget between engaged and forecasted**