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Nestlé Business Outsourcing Management organization

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Nestlé Research™

Glossary

AE - Adverse Event
BIOM - Biometry
BOM – Business Outsourcing Management
BST – Biostatisticians
CAPA – Corrective and Preventive Actions
CDISC – Clinical Data Interchange Standards Consortium
CDM – Clinical Data Managers
CDMS – Clinical Data Management system
CDU – Clinical Development Unit
Clinops - Clinical Operations
CPM – Clinical Project Managers
CTDC2 – Clinical Trial Decision Committee 2
CTMS – Clinical Trial Management system
DB - Database
KOM – Kick-Off Meeting
iDMC – Independent Data Monitoring Committee
ICU – Intensive Care Unit
IP – Intellectual Property
IT - Information Technologies
LSFV – Last Subject First Visit
LSLV – Last Subject Last Visit
MSA - Master Service Agreement
NRC – Nestlé Research Center
ORM – Operational Review Committee
PM – Project Manager
SAE – Serious Adverse Event
SAP – Statistical Report
SAS - Statistical Analysis System
SOP - Standard Operating Procedure
SPOC – Single point of contact
SR – Statistical Report
SSU – Study Setup
WO – Work Order

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Introduction

- Clinical Development Unit (CDU): *Dedicated to Clinical Development and Global execution of Clinical Research to strengthen Nestlé' s leadership in Nutrition, Health and Wellness*
- Department: 45 CDU Employees - 35 Clinical Operations Members
- Location: Vers-chez-les-Blanc (Switzerland), Florham Park (USA), Beijing, Singapore

Introduction con't: Clinical Operations

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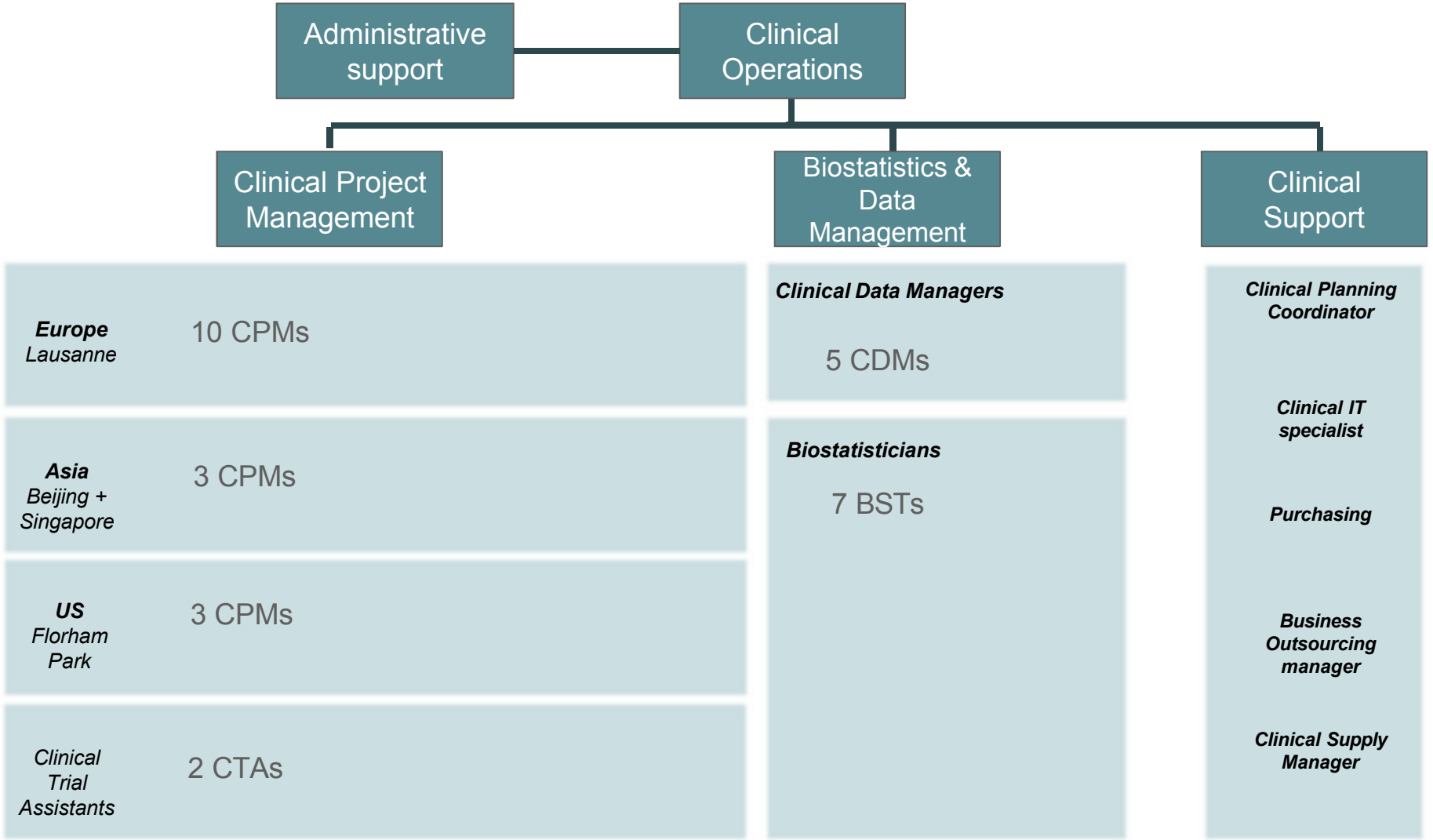

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Nestlé Investigational Products

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Products category	Some key or active tested ingredients
Infant Formula	Protein level, Milk protein (casein, whey), Probiotics, Prebiotics, CMOS/GOS, Oligosaccharides, Extensively hydrolyzed formula, Palmitic acid, Lipid fractions
Human milk fortifier	Partially hydrolyzed whey protein
Probiotics	i.e. B.Lactis
Cereals	Fibers, Iron, Zinc, Vitamin A, Phytochemicals
Coffee, Green Tea	Cafeine, Chlorogenic and Phenolic acids, Epicatechin, Polyphenols
Chocolate	Cocoa Polyphenols, Maltodextrin, Epicatechin
Plant extracts	Beta-glucans, Nopal polysaccharides, Capsaicin (chilly peppers), Amaranth flour, Iron Fortified Cowpea, Spirulina
Dietary Supplement	Lactose Intolerance, Probiotic for Seasonal Allergic Rhinitis, Arginine, n-3 and Nucleotides, Omega-3 fatty acids, Food fibers, Long chain polyunsaturated fatty acids (LC-PUFA), Sterols and hawthorn powder, Phenolic acid, Hesperidin
Performance nutrition	Fructose, Micellar whey protein, Glycine, Citrulline, Beta-alanine
Brain health	Hydration, Medium-chain triglycerides (MCTs), DHA, Lutein, Choline
Body weight	Fibers, Sugar and fat reduction, Meal replacements, Probiotic formulation
Enteral feeding	Macronutrients, Micronutrients, Glutamine
Health Care Nutrition	Amino acids, Micronutrients, Fish oil, Phytosterol, Medium Chain Triglycerides

Nestlé Product categories - for more information, refer to ***ClinicalTrials.gov***

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Objective

Enhance the outsourcing governance and cost forecasting by centralizing the businesses synergies in the Clinical Operations

Prerequisites

- Review of contracts by Experts, in case of issues – Biostatisticians, Clinical Project and Data Managers, IT Specialists, Safety Managers
  - ➢ 1 to 1 discussions with Experts
- Budget constraints,
- Resources Flexibility.

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Drivers for sustainability

- Nestlé workload review feeding the Outsourcing Volume
  - Work volumes increase for leveraging price reduction
  - Coordination: Procurement / Legal / Contract Management Office
- Study assessment of outsourcing risk and opportunities by the Clinical Teams via the outsourcing evaluation log
- Outsourcing strategy and core /non –core activities defined within the Clinical Operations

Outsourcing Strategy – Objectives and Drivers con't

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Core activities

Clinical study design – e.g.:

- ✓ Outline and Protocol – CPM, CDM, BST
- ✓ Statistical analysis Plan – BST
- ✓ Data Listing, subject diaries – CDM
- ✓ Data Validation Plan – CDM
- ✓ CDISC Mapping – CDM
- ✓ Study planning - CPM

Clinical study quality – e.g.:

- ✓ Study risk assessment and quality control of the trial - CPM, CDM, BST, Quality Assurance
- ✓ CAPA analysis – CPM, CDM, BST
- ✓ Data reports quality review - CDM
- ✓ Quality control and approval of Statistical reports CPM, BST
- ✓ Manual queries management - CDM
- ✓ Study lock/freeze - CDM
- ✓ Trial Master file – CPM, CDM, BST

Safety and regulatory affairs – e.g.:

- ✓ informed consent – CPM
- ✓ SAE review and reporting – CDM, Medical Officer
- ✓ Coding AE/SAE review and approval - CDM, Medical Officer

Communication with Nestlé and external stakeholders – e.g.:

- ✓ Project Lead and coordination - PM/CPM
- ✓ Clinical Study meeting Lead – CPM, CDM, BST
- ✓ Manual queries management - CDM
- ✓ Ethic Committees submissions – CPM
- ✓ Site, laboratory and product factory selection – CPM
- ✓ Laboratory manuals - CPM
- ✓ Electronic data transfers agreements – CDM
- ✓ Supplies/product specifications and shipment plans – CPM
- ✓ Publications

IT

- ✓ Clinical Data Management System (CDMS), Clinical Trial Management System (CTMS), Safety System (Aris g), Planning and Resources System (Primavera)

Non-Core activities

Clinical study design – e.g.:

- ✓ Support in study design and quality documents preparation
- ✓ Database setup,
- ✓ CDISC conversion,

Clinical study quality – none

Safety and regulatory affairs – none

Communication with Nestlé stakeholders – e.g.:

- ✓ Study Monitoring,
- ✓ Automatic query management,
- ✓ Sample, product and supply management and reporting (shipment/production logs)
- ✓ Site proposal,
- ✓ Laboratory data analyses,
- ✓ Laboratory files management,
- ✓ Sample management,
- ✓ Monitoring and statistical Reports,
- ✓ Participation in meetings and meeting minutes writing,
- ✓ and so on.

Business Outsourcing strategy

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CDU Outsourcing strategy

Decisional algorithm: Outsourcing scope and Partner

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- **Responsible**

The Clinical Team and Clinical Operations Management evaluate the risk and opportunities related to the outsourcing of the clinical study operations for each and every study. Based on all recommendations and feedbacks the Business Outsourcing Manager takes the decision on the outsourcing scope and Partner accordingly.

- **Timing**

Further to the study design definition and before the decision of performing the clinical study.

- **Support**

8 Question based recommendatory score for outsourcing + traceability of clinical team's recommendation and Management decisions.

Decisional algorithm: Outsourcing scope and Partner

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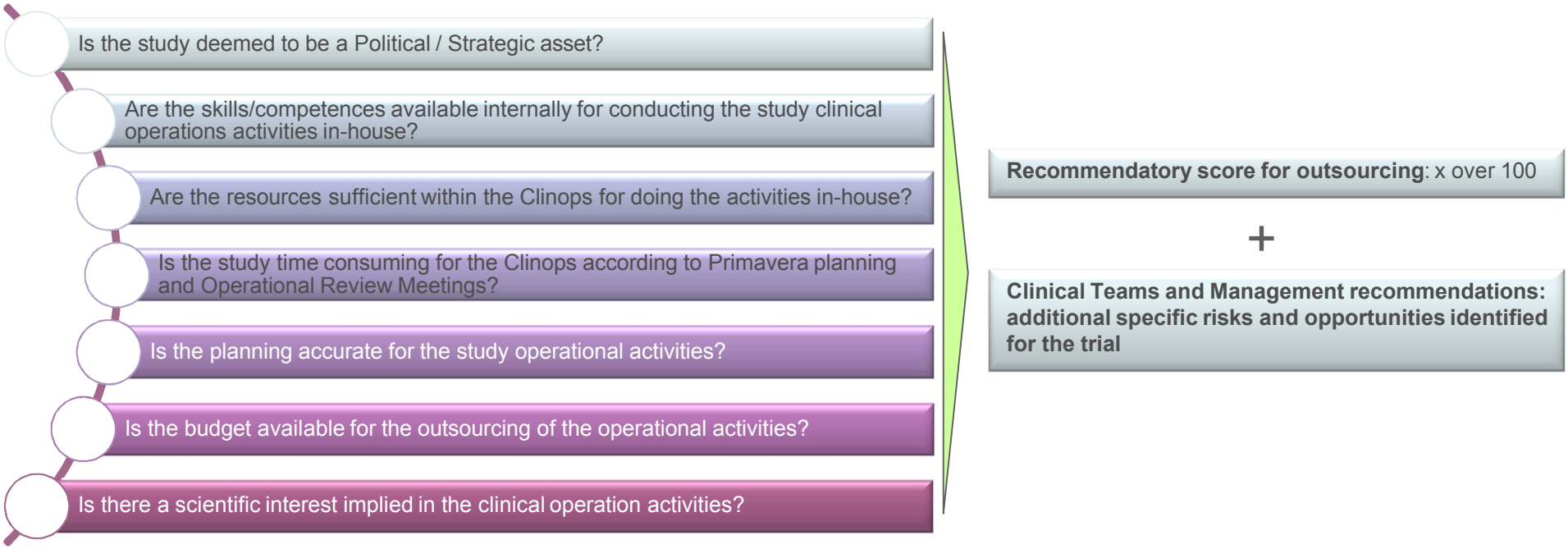
- **Steps**

Step 1: Trial risks and opportunity assessment review by the Clinical Team



Outsourcing evaluation log schema

Step 2: Workload and planning review by the Clinical Operations Management

Step 3: Decision taken on the outsourcing scope by the Business Outsourcing Manager – based on all recommendations and feedbacks

Decisional algorithm: Outsourcing scope and Partner con't

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Study	CPM	CDM	BST	#	Criteria	Scale 1 (low) to 4 (high)	Priority	Weight	Reverse scoring applied	Score	Instructions
Trial Number	CPM initials	CDM initials	BST initials	1	Is the study deemed to be a Political / Strategical asset?	1	2	4	Yes	4	COMPLETED BY THE CLINICAL TEAM BEFORE THE ORM 4= Part of NRC top priority project or identified as such by the CDU Management 3= Related to a project involving Product Marketing Authorization dossier or commercialization depending on study results 2= Related to a Health claim only or testing a new data capture technique else 1
				2	Are the skills/competences available internally for conducting the study biometrics activities inhouse?	2	2	4	Yes	3	COMPLETED BY THE CLINICAL TEAM BEFORE THE ORM 4= No biometrics related risk 3= at least 1 biometrics related green risk, 0 yellow risks and 0 red risks 2= at least 1 biometrics related yellow risk and 0 red risks 1= at least 1 biometrics related red risk in the risk management grid
				3	Are the skills/competences available internally for conducting the study Clinical Project management activities and /or medical activities inhouse?	2	2	4	Yes	3	COMPLETED BY THE CLINICAL TEAM BEFORE THE ORM 4= No CPM and/or Medical related risk 3= at least 1 CPM and/or Medical related green risk, 0 yellow risks and 0 red risks 2= at least 1 CPM and/or Medical related yellow risk and 0 red risks 1= at least 1 CPM and/or Medical related red risk in the risk management grid
				4	Are the resources sufficient within CDM for doing the activities inhouse?	2	1	5	Yes	3	COMPLETED BY THE GROUP LEADER before the outsourcing decision 4= Availability of the Team above 30% between DB setup and DB Go live and / or between LSLV and DB lock, when the finalization is within 3 months from the date of assessment. 3= Availability of the Team between 20 and 30% between DB setup and DB Go live and / or between LSLV and DB lock, when the finalization is within 3 months from the date of assessment. 2= Availability of the Team below 20% between DB setup and DB Go live and / or between LSLV and DB lock, when the finalization is within 3 months from the date of assessment. 1= Red histogram on the Team between DB setup and DB Go live and / or between LSLV and DB lock, when the finalization is within 3 months from the date of assessment.
				5	Are the resources sufficient within Biostatistics for doing the activities inhouse?	2	1	5	Yes	3	COMPLETED BY THE GROUP LEADER before the outsourcing decision In case there is a need of an independent external statistician and / or an IDMC with unblinded interim Statistical analysis is planned please put 4, else: 4= Availability of the Team above 30% between KOM and Protocol finalization and / or between start of SAP writing to SR completed, when the SAP writing is within 3 months from the date of assessment. 3= Availability of the Team between 20 and 30% between KOM and and Protocol finalization and / or between start of SAP writing to SR completed, when the SAP writing is within 3 months from the date of assessment. 2= Availability of the Team below 20% between KOM and and Protocol finalization and / or between start of SAP writing to SR completed, when the SAP writing is within 3 months from the date of assessment. 1= Red histogram on the Team between KOM and and Protocol finalization and / or between start of SAP writing to SR completed, when the SAP writing is within 3 months from the date of assessment.
				6	Are the resources sufficient within CPM for doing the activities inhouse?	2	1	10	Yes	3	COMPLETED BY THE GROUP LEADER before the outsourcing decision 4= Availability of the Regional Team above 30% between KOM and Protocol finalization and / or between LSFV to SR completed, when LSFV is within 3 months from the date of assessment. 3= Availability of the Team between 20 and 30% between KOM and and Protocol finalization and / or between LSFV to SR completed, when the SAP writing is within 3 months from the date of assessment. 2= Availability of the Team below 20% between KOM and and Protocol finalization and / or between LSFV to SR completed, when the LSFV is within 3 months from the date of assessment. 1= Red histogram on the Team between KOM and and Protocol finalization and / or between LSFV completed, when the LSFV is within 3 months from the date of assessment.
				7	Is the study time consuming for Biometrics- according to Primavera planning and ORM?	1	4	2	No	1	COMPLETED BY THE PLANNING SPECIALIST before the outsourcing decision 4= CDM and BST Effort =template + 5 working days or above between KOM and DB go Live and / or between start of SAP writing to SR completed, when the SAP writing is within 3 months from the date of assessment. 3= CDM and BST Effort =template + 3 to 4 working days between KOM and DB go Live and / or between start of SAP writing to SR completed, when the SAP writing is within 3 months from the date of assessment. 2= CDM and BST Effort =template + 1 to 2 working days between KOM and DB go Live and / or between start of SAP writing to SR completed, when the SAP writing is within 3 months from the date of assessment. 1= CDM and BST Effort =template + 0 working days between KOM and DB go Live and between start of SAP writing to SR completed, when the SAP writing is within 3 months from the date of assessment.
				8	Is the study time consuming for CPMs – according to Primavera planning and ORM?	2	4	2	No	2	COMPLETED BY THE PLANNING SPECIALIST before the outsourcing decision 4= CDM and BST Effort =template + 5 working days or above between KOM and DB go Live and / or between start of SAP writing to SR completed, when the SAP writing is within 3 months from the date of assessment. 3= CDM and BST Effort =template + 3 to 4 working days between KOM and DB go Live and / or between start of SAP writing to SR completed, when the SAP writing is within 3 months from the date of assessment. 2= CDM and BST Effort =template + 1 to 2 working days between KOM and DB go Live and / or between start of SAP writing to SR completed, when the SAP writing is within 3 months from the date of assessment. 1= CDM and BST Effort =template + 0 working days between KOM and DB go Live and between start of SAP writing to SR completed, when the SAP writing is within 3 months from the date of assessment.
				9	Is the planning accurate for the study operational activities?	2	1	1	No	2	COMPLETED BY THE CLINICAL TEAM BEFORE THE ORM 4= no risk of planning variability 3= Risk of planning variability low 2= Risk of planning variability medium 1= Risk of planning variability high
				#	Is the budget available for the outsourcing of the operational activities?	3	4	1	No	3	TO BE COMPLETED BY THE BOM before ORM 4= Budget exceeding as per last quarter review 3= Budget available as per last quarter review 2= Limited budget available as per last quarter review 1= No budget available as per last quarter review
				#	Is there a scientific interest implied in the study biometrics activities?	1	1	3	Yes	4	COMPLETED BY THE CLINICAL TEAM BEFORE THE ORM 4= Confirmed decision to have CDM data capture new technique involved and new BST Analysis method to be validated - decision yet to be taken before CTDC2 - budget to be checked with the IT Specialist 3= Confirmed decision to have CDM data capture new technique involved or new BST Analysis method to be validated - decision yet to be taken before CTDC2 - budget to be checked with the IT Specialist 2= Routine trial, but opportunities to have CDM data capture new technique involved and/or new BST Analysis method to be validated - decision yet to be taken by the Clinical Team - potential budget to be checked with the IT Spec 1= Routine trial, no CDM data capture new technique involved no new BST Analysis method to be validated
					Total over 100 for Biometry	77					
					Total over 100 for Clinical Project Management	79					
					Total over 100 for Full Package	75					
					Recommendations For the decision	SAFETY : ICU unit patient – a lot of safety involved safety regulatory board – CDM implication for data collection maybe involved: consulting services already devised.					
					Decision						

Completed outsourcing evaluation log example

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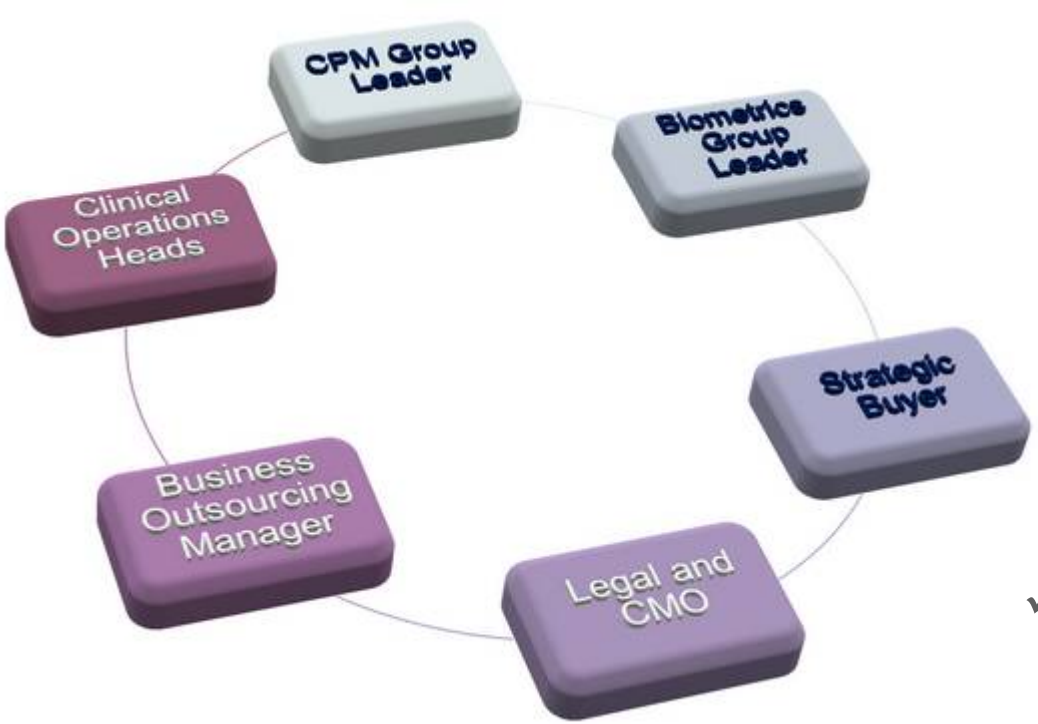
Cross-Functional collaborative Team



Inter-functional Team – Preferred Partners selection

- ✓ Selected Preferred Partners
  - ➢ Large-size, global CRO
  - ➢ Biometrics: Mid-size & small-size, local CROs
- ✓ Final step of selection
  - ➢ Mid-size, global CROs

Business Outsourcing Manager missions

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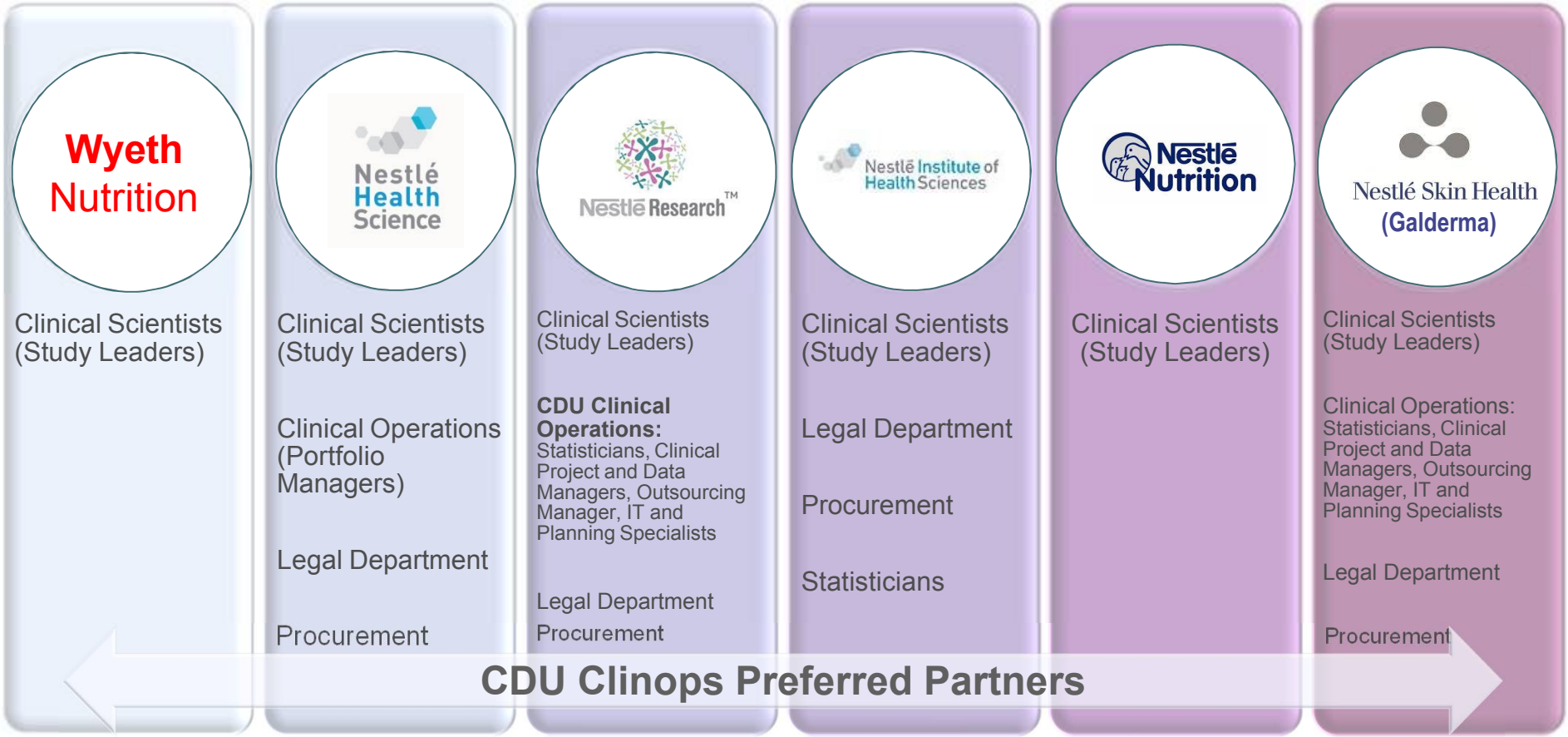
- Increase the outsourcing Productivity by converging the working volume of all Nestlé Businesses to the Clinical Operations Preferred Partners – integrating all organizational clusters.
- Allow cross-businesses and cross-studies ad-hoc analyses - External parties access given to Nestlé Systems
- Contract templates (MSA/WO), negotiation and Governance processes coordinated by the Clinical Operations



Nestlé Businesses: Clinical Study Management related functions

Preferred Partners/CRO supervision by the Clinops

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Before, towards and after the course of the outsourced services …

Services & Quality

- ✓ Global geographical service coverage
- ✓ Selection, day to day management and governance of all activities by Clinops Experts
- ✓ Delivery Acceptance procedure – Validation of deliverables by Clinical Operations Experts
- ✓ Key performance indicators and CAPA
- ✓ Full data control, as in our systems

Synergies

- ✓ Ensure the Partner's increase of productivity and quality of deliverables
- ✓ Leverage quality and cost savings – joint negotiation (Galderma) efforts with all Nestlé entities
- ✓ Secure Partner's staff retention (CDU dedicated resources and flex Resources)

CDU

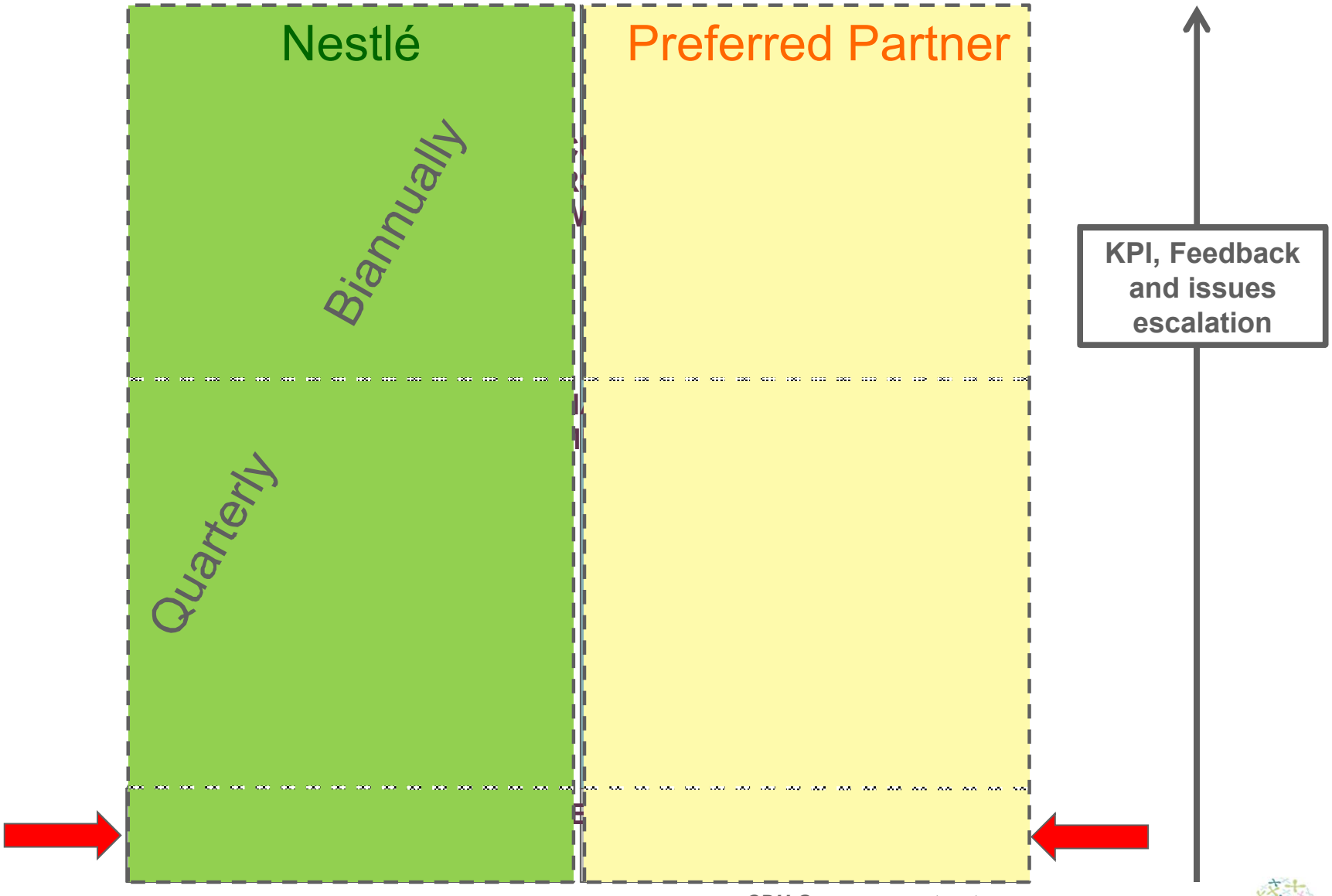
Cost Control

- ✓ Delivery based payment schedule
- ✓ Payment of the lowest of price per deliverable and hour cost
- ✓ Contract Stipulating the costless reuse of co-developed standards (IP management)

Audit

- ✓ Warrants Nestlé readiness for an Audit: traceability of all activities, effective deliverables, archiving and so on
- ✓ Audit of Partners by Professional and Experts

Governance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Preferred Partner
Biannually
Quarterly
KPI, Feedback and issues escalation

Governance, escalation and KPI tracking by function

- Purpose
  - Control the deliverables quality
  - Continuous improvement of the services and productivity
    - CAPAs, new metric(s) introduction a.s.o…