

PCMG Workshop

8thOct2015

Outsourcing Model, LEO Case

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From Full Outsourcing to Functionel Outsourcing

LEO Pharma today



Around 5,000 employees in
61 countries

Products sold in more than
100 countries

Headquarters,
Ballerup

Historic milestones of LEO Pharma

Origin

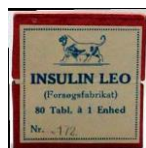
A. Antons
& A.
Kongsted
establish
LEO
Pharma



Painkiller
Albyl®
marketed



Insulin
production
begins



1908

1912

1923

Early biotech

Heparin
LEO®
marketed



Penicillin
LEO®
marketed



LEO begins
exporting
globally



LEO
Foundation
established



1940

1945

1949

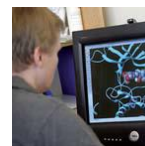
1983

Global

Daivonex®
(Dovonex®,
Talconex®)
& innohep®
launched



An R&D
complex
with
state-of-
the-art
facilities is
built
in Ballerup



Daivobet®
(Dovobet®)
launched



1991

1998

2001

Onwards

LEO
acquires
biotech
company
Peplin, Inc.



LEO growth
strategy
launched
introducing
substantial
growth
ambitions
in markets,
products
and people



2009

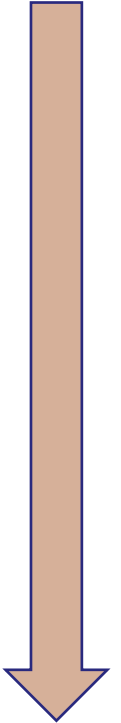
A close-up photograph of a person's back and shoulder, showing their skin texture and a silver hoop earring. The person has dark hair. The background is dark.

Our growth strategy is
built on putting **patients**
in the centre of everything
we do!

Outsourcing at LEO Pharma

6

- <2006 Only Central Lab and Phase I Trials
- 2006 Outsourcing department established
- 2007 reduction of Clinical operations in affiliates
- 2009 Consolidation of Outsourcing Department (split from BD)
- 2012 Partnership Management



Increasing Outsourcing

Outsourcing Strategy until 2012

Phase III - Only



Mixed model Full and Functional

	Phase II-III trials
Full Outsourcing	<ul style="list-style-type: none">• Clinical trials conducted in countries outside satellite countries (AU, CA, DE, FR, UK)• All clinical trials with more than approx. 100 subjects and/or depending of the complexity of the study design
In-house	<ul style="list-style-type: none">• Clinical trials up to approx. 100-400 subjects conducted in satellite countries only (AU, CA, DE, FR, UK) and/or depending of the complexity of the study design

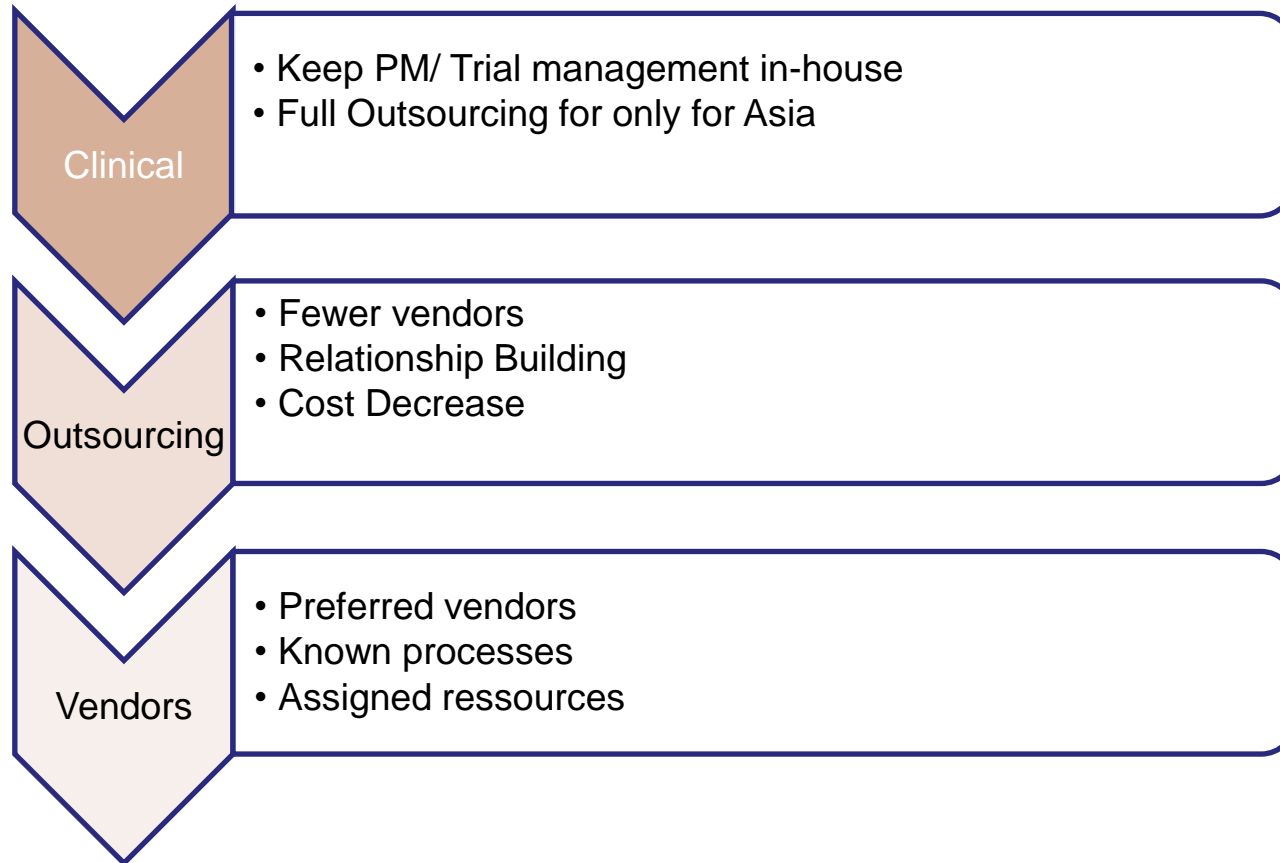
From 2013 - Functional Outsourcing

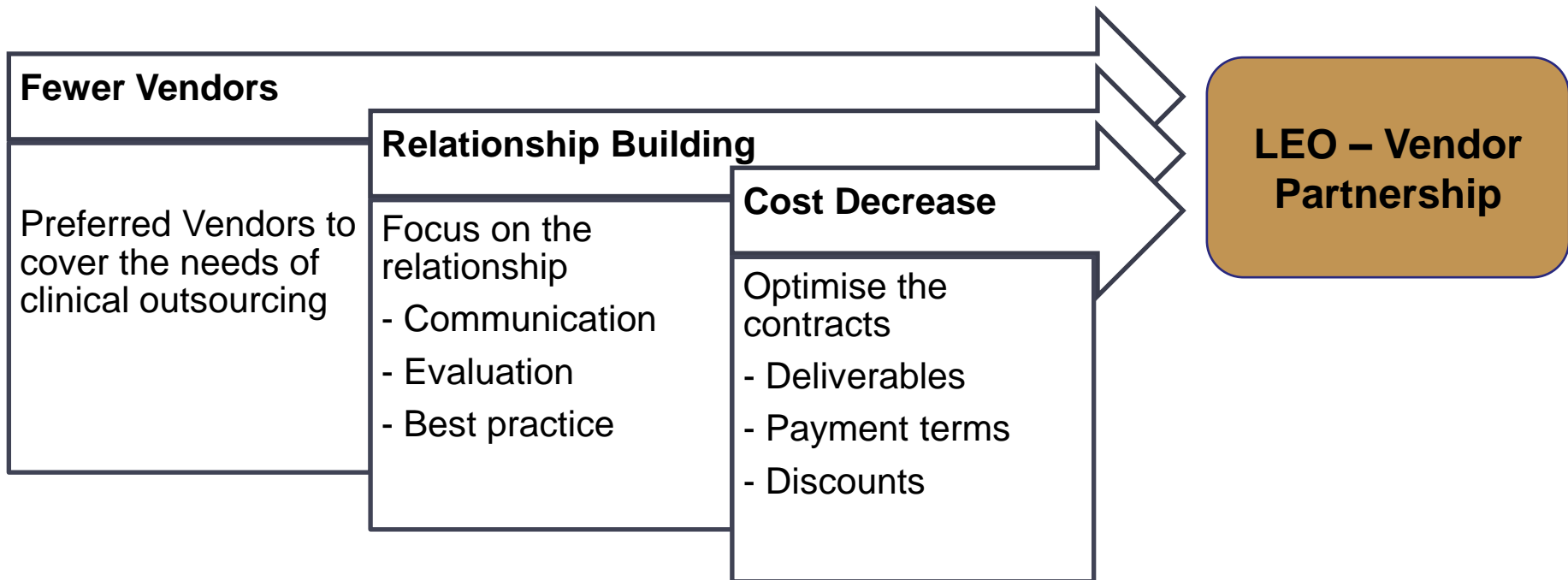
Outsourcing Strategy - for PHII trials

2 January 2016

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From 2013





Which Services can be Functionally Outsourced

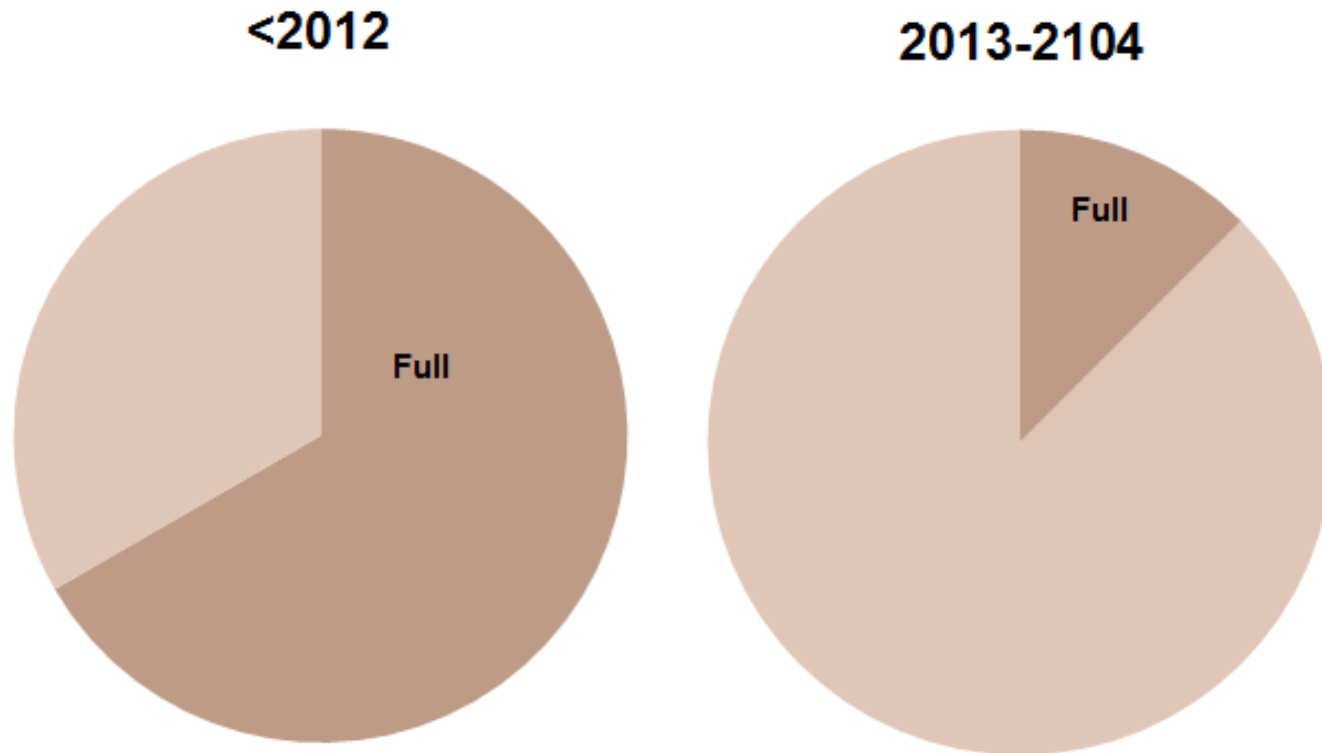
Functional Outsourcing Services	
Central Laboratory	IWRS
CTS	Medical monitoring
Data management	Medical writing
ECG	Photography
ePRO	Recruitment management
Clinical Monitoring /CRAs	

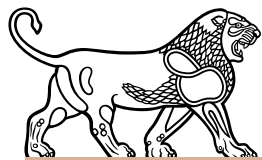
Clinical Trials

28 January 2016

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Change of Full Outsourcing and Functional Outsourcing





Case study

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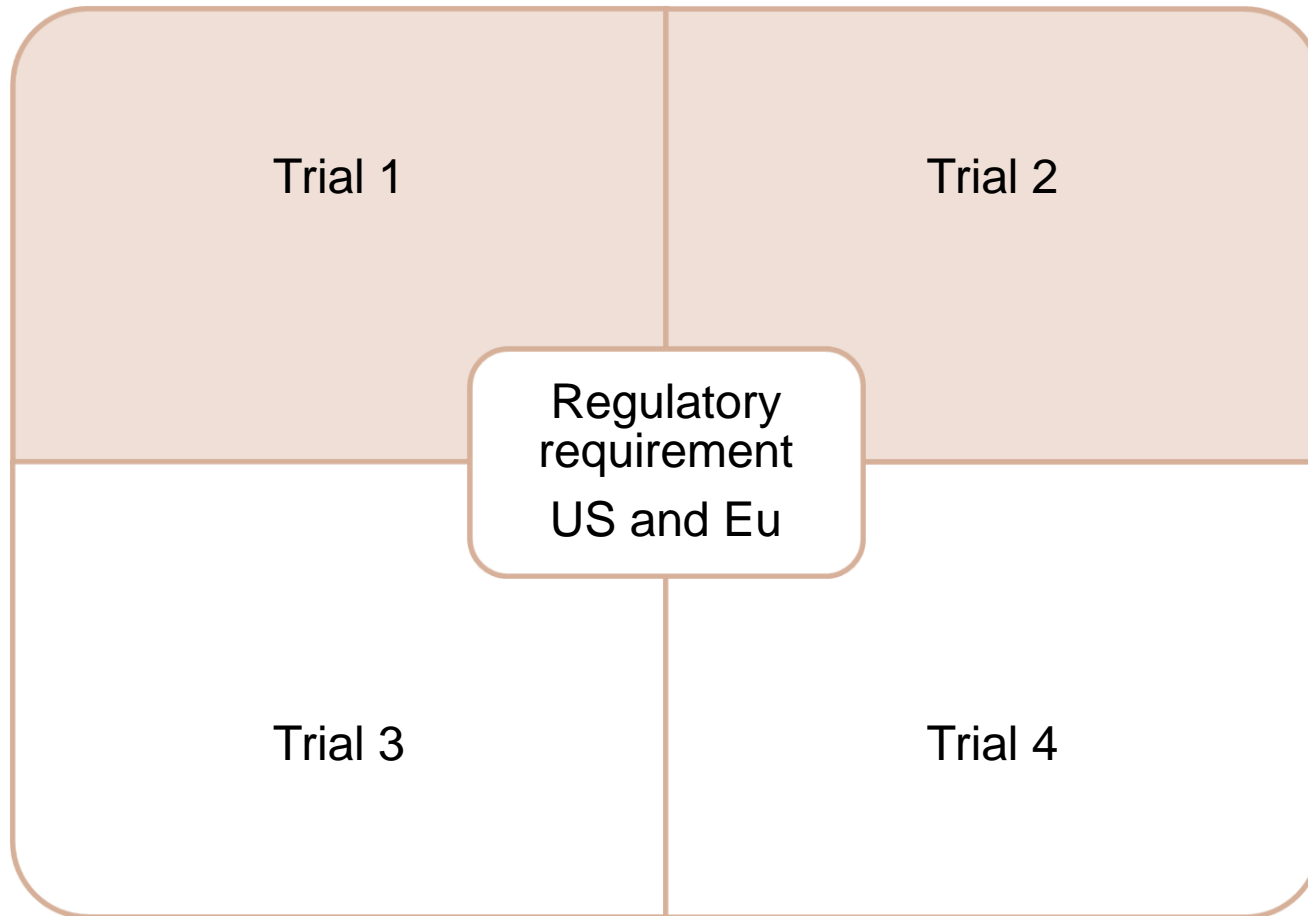
4 Trials

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Indication: Actinic Keratosis

FPI Nov 15



Outsourcing role

- Each Outsourcing Manager assigned to specific functional areas
- Information stream between the trials, team members and Outsourcing Manager
- Vendor management role change e.g trial overview, missing information

Outsourcing role

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Outsourcing activities

6 Outsourcing managers assigned

Each Outsourcing manager works directly with the assigned operational functional lead

1 Lead Outsourcing manager attends Trial meeting across all trials

Program Operations Team Meeting

Trial Team meeting

All meeting minutes are shared with the outsourcing team

Weekly internal coordination meeting across all services

Learnings

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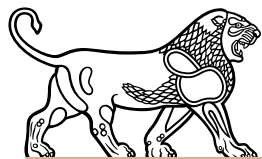
Communication

Contracting process

Relationship

Change from Full Outsourcing to Functional Outsourcing

- Workload
 - Coordination
 - Communication
 - Collaboration
 - Processes and templates
-
- 2016 – Lessons learned



Thank you

Questions?

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