

From GAP to opportunity





PharmaNL

From gap to opportunity

How the PharmaNL gap analysis can support innovation

Core partners

- **Pivot Park – Brigitte Drees**
- **Campus Groningen – Ton Vries**
- **Universiteit Leiden – Hubertus Irth**
- **Supported by FAST – Benien Vingerhoed**

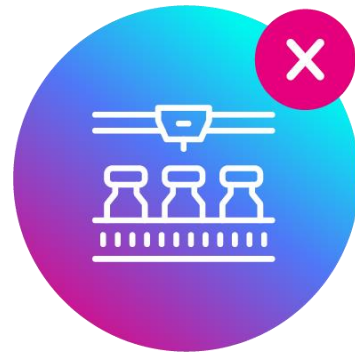
Developed in cooperation with the Ministry of VWS, and submitted by VWS, with support from EZK, to the National Growth Fund (2nd round).



Marieke Meulemans
Programme manager PharmaNL

Why? Growth and earning potential underutilized

The growth potential and earning potential of the Dutch Life Sciences sector is currently not effectively used.



Infrastructure

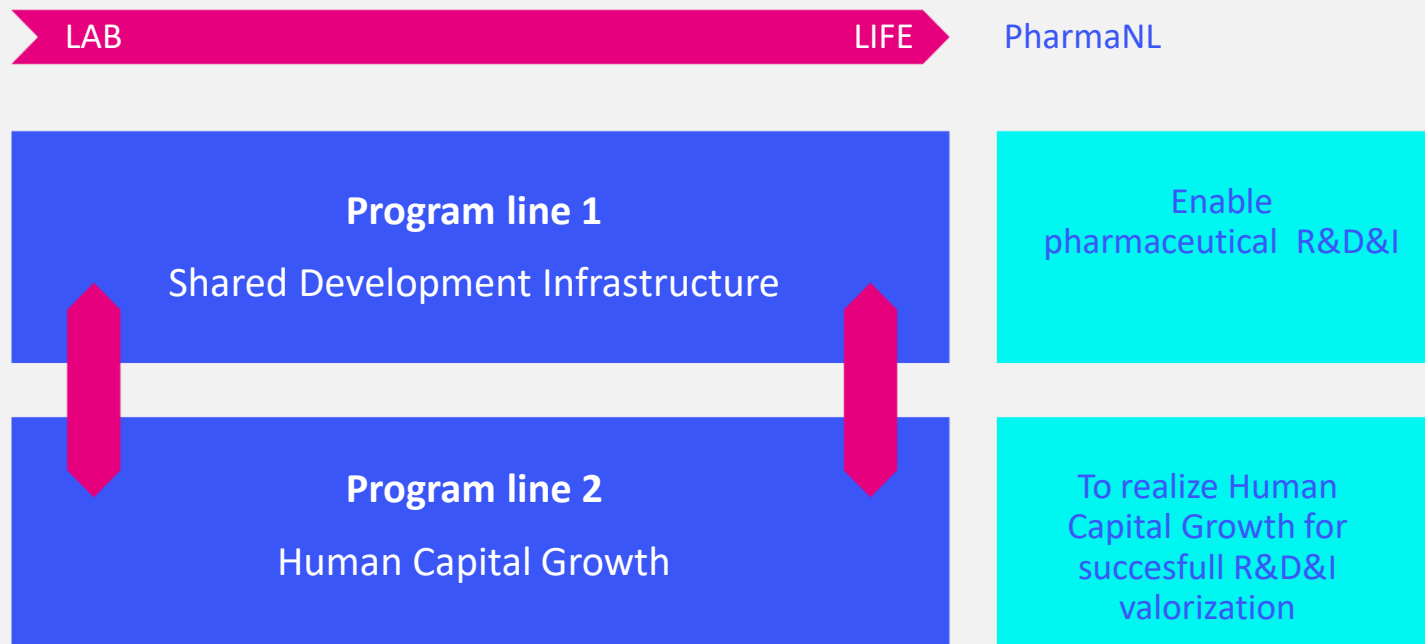
Insufficient availability of easily accessible high-quality infrastructure for development of promising innovative pharmaceutical products and production technologies



Human Capital

Shortage of properly qualified personnel to deliver these new pharmaceutical products and to exploit production technologies on Dutch soil.

2 PharmaNL programmes

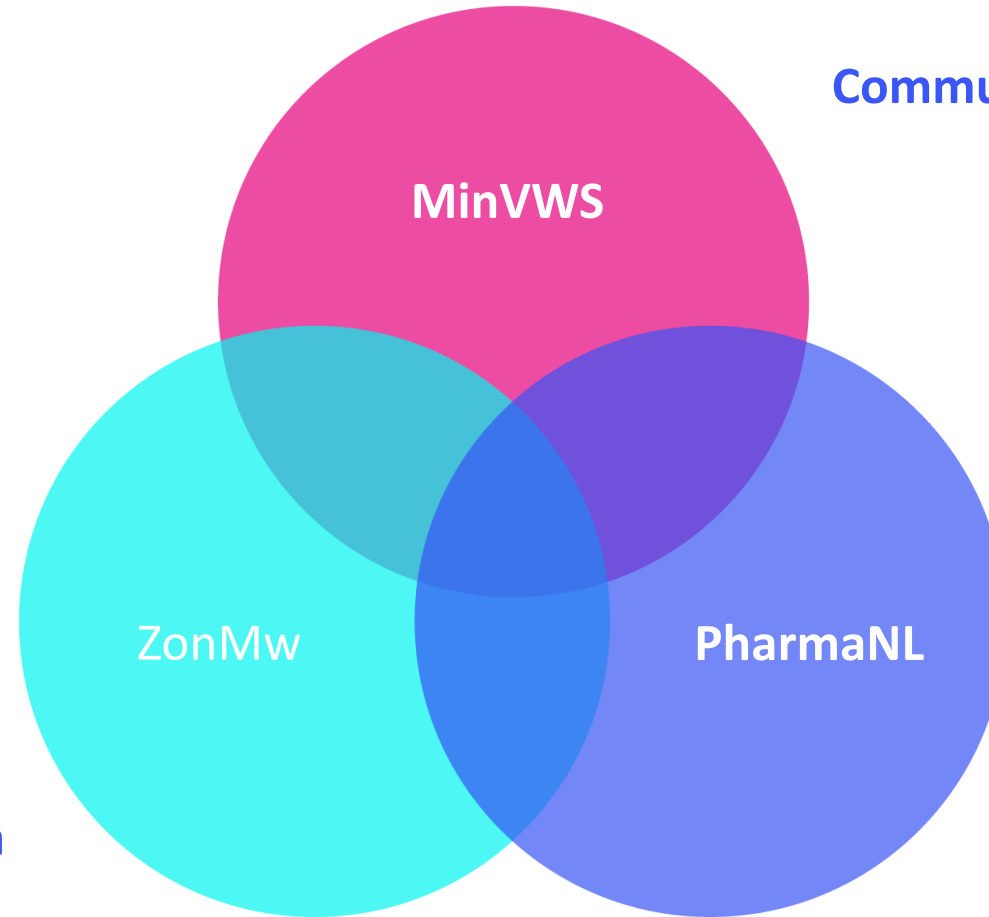


- **Euro 78,8 mio** period 2024-2032
- To give a **sustainable boost** to benefit from the economic potential of innovative pharmaceutical products and product technologies
- **To improve the size and quality of the sector**
- To improve the **attractiveness** of the sector for pharma and biotech companies

Roles and responsibilities

Applicant at NGF

Communicates with NGF via EZK



Assesment of the applications

Distributing the funds via the calls

Initiator

Strategy

Guidance

GAP analysis – define priorities

Contact with the field



PharmaNL | infrastructure

Objective SDI Programme

to make available high-quality and innovative infrastructure facilities that are essential for groundbreaking pharmaceutical product and production technology developments in areas in which the Netherlands has a strong starting position, and for which the required R&D facilities and services are not available and/or will not be established under regular market forces.

PharmaNL - Shared Development Infrastructure



Geneesmiddelen

Infrastructuur

Medicijnen

Talentontwikkeling en vrij onderzoek

Translatieel onderzoek

Kenmerken

Status: In uitvoering

Budget: € 57.000.000

Looptijd: 17%

2023

2030

Onderdeel van programma:

[PharmaNL](#)

[PharmaNL - Human Capital Growth](#)



<https://www.zonmw.nl/nl/programma/pharmanl>

Het PharmaNL Shared Development Infrastructure (SDI) programma richt zich op het opzetten van geavanceerde infrastructuur voor gedeeld gebruik door farmaceutische start-ups, scale-ups en academische onderzoeksgroepen.



PharmaNL | human capital

Objective HCG Programme

to train sufficient suitably qualified personnel (5000) for the Dutch pharmaceutical value chain. Through strengthening cooperation between industry and educational institutions, enabling a demand driven setup of education on post-MBO, -HBO and -Academic level. And resulting in high-quality hybrid and life-long-learning opportunities.



PharmaNL - Human Capital Growth



Het PharmaNL Human Capital Growth (HCG) programma richt zich specifiek op het realiseren van een vraaggestuurde groei van het aantal personen dat een PharmaNL opleiding of PharmaNL onderwijs zal volgen.

Onderwerpen

Geneesmiddelen

Infrastructuur

Medicijnen

Opleiden, leren en professionaliseren

Talentontwikkeling en vrij onderzoek

Translatieel onderzoek

Kenmerken

Status: In uitvoering

Budget: € 14.900.000

Looptijd: 10%



Onderdeel van programma:

[PharmaNL](#)

[PharmaNL - Shared Development](#)

[Infrastructuur](#)

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Projecten van start binnen PharmaNL Human Capital Growth

 Nieuws | februari 20, 2024

Update 30 april, 2024

'Life-long learning programma voor post-graduate biomedische en farmaceutische professionals'

Leiden University Medical Center

'Early Drug Discovery Education Track'

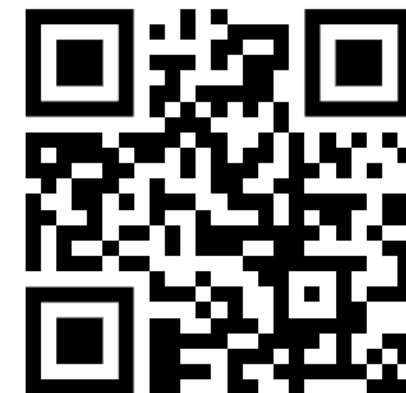
HAN, RadboudUniversity Nijmegen, Pivot Park en Elevate

'Groningen Human Capital for Life Sciences'

LIFE Cooperative, Hanzehogeschool Groningen en het UMCG

Evaluatierapport PharmaNL HCG

CALL 2023-1





- Requirements
- ZonMw General Grant Provisions
 - State aid rules

• Call 1 on invitation ~ €20 mln (in assessment)

- Call 2 starts in 2025
- Call 3 starts in 2026
- Call 4 starts in 2027



€ 37 mln

Max € 5 mln subsidy per SDI grant application
~ 50% subsidy (AGVV)

• Call 1 on invitation ~ € 3.1 mln

- Call 2 starts Q4 2024 ~ €5.9 mln
- Call 3 starts in 2026/27 ~ €5.9 mln

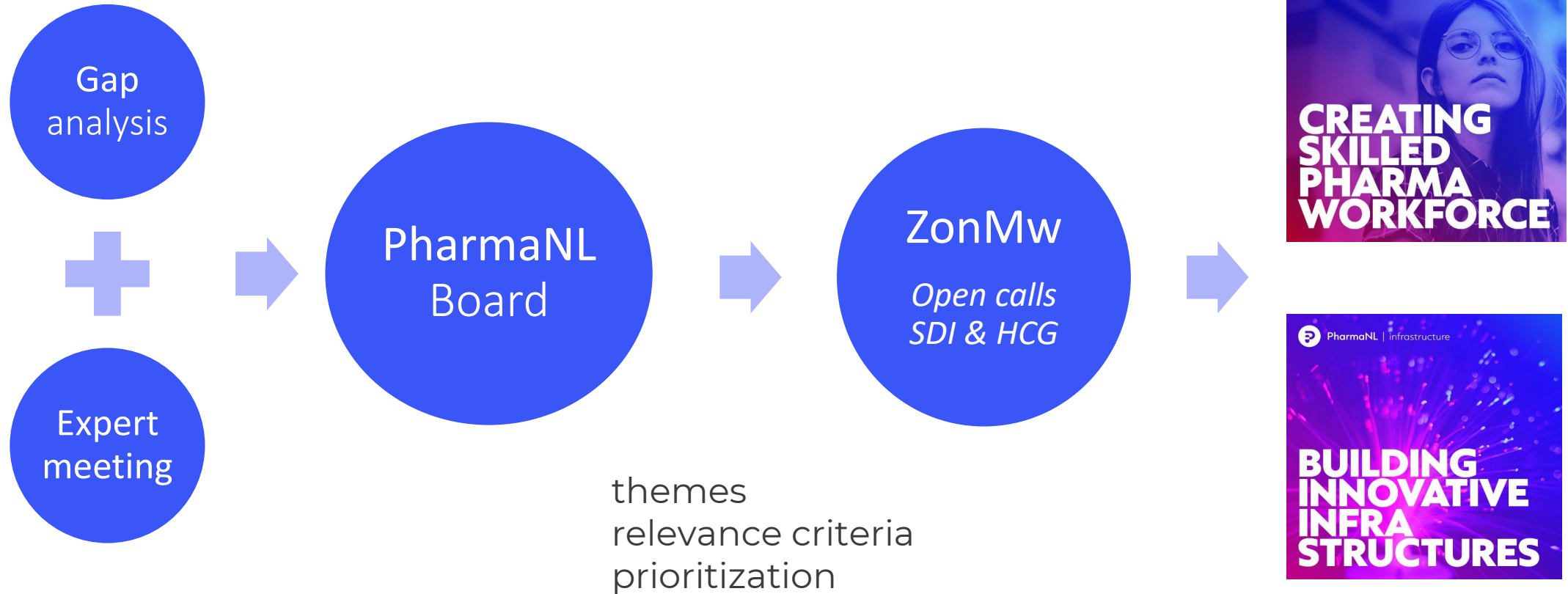
Max € 1 mln subsidy per HCG grant application
~ 50% subsidy (AGVV)



PharmaNL

gap analysis

Demand driven: from input to impact



Drug development proces

Drug Discovery, Development, and Deployment Map
Wagner et al.

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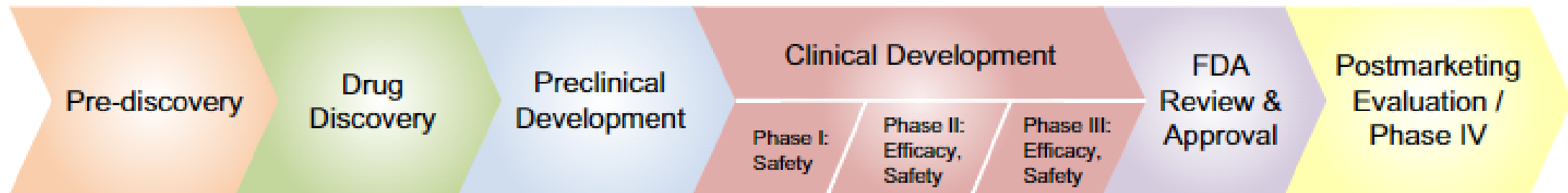


Figure 1 Therapeutic development chevron diagram. Traditional chevron diagram representation of therapeutic development. Colors in this chevron correspond to the associated “neighborhoods” on the Drug Discovery, Development, and Deployment Map. FDA, US Food and Drug Administration.

4D Map

- The Drug Discovery, Development, and Deployment Map (4DM)
- Developed in 2017 by The Forum on Drug Discovery, Development, and Translation of the US National Academies of Sciences, Engineering, and Medicine in the US
- Published in *Nature Reviews Drug Discovery*
- A dynamic map for learning, communicating, navigating and improving therapeutic development

Drug Discovery, Development, and Deployment Map
Wagner et al.

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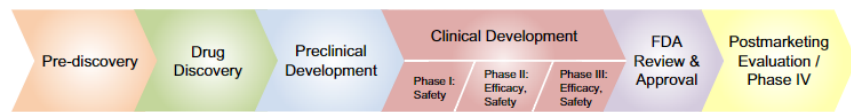
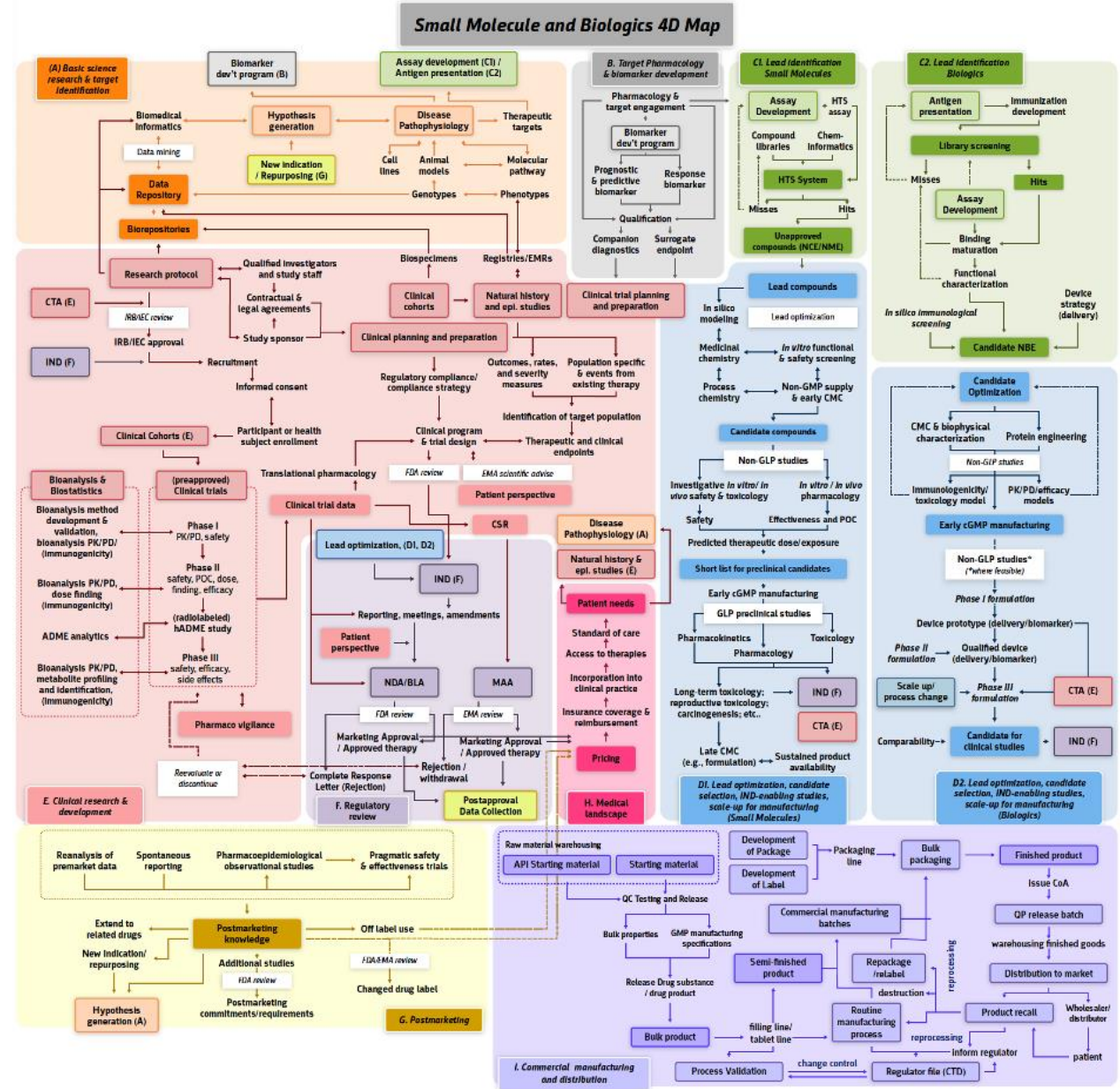


Figure 1 Therapeutic development chevron diagram. Traditional chevron diagram representation of therapeutic development. Colors in this chevron correspond to the associated "neighborhoods" on the Drug Discovery, Development, and Deployment Map. FDA, US Food and Drug Administration.



<https://www.nature.com/articles/nrd.2017.217>

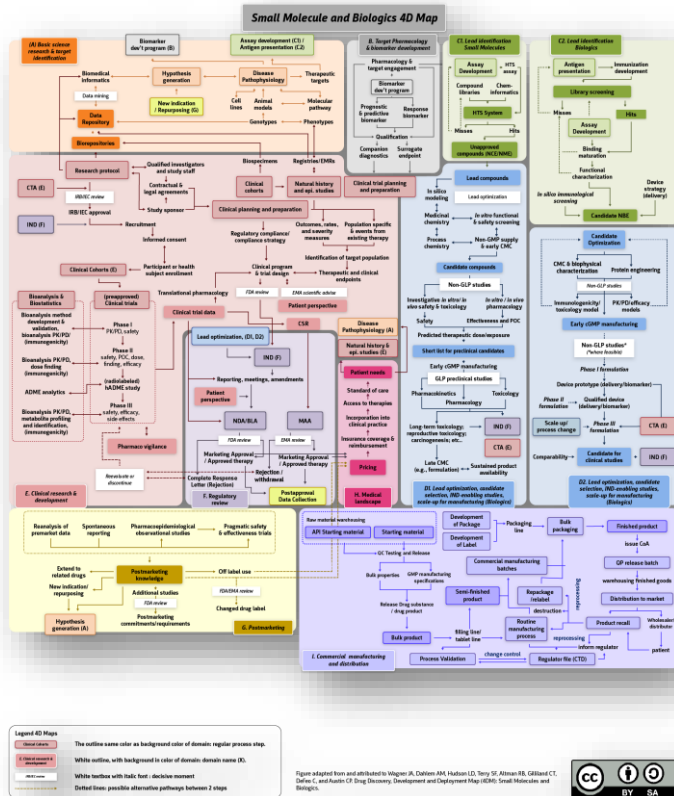


From map to questionnaire tool

4D Map Small Molecule & Biologics Development

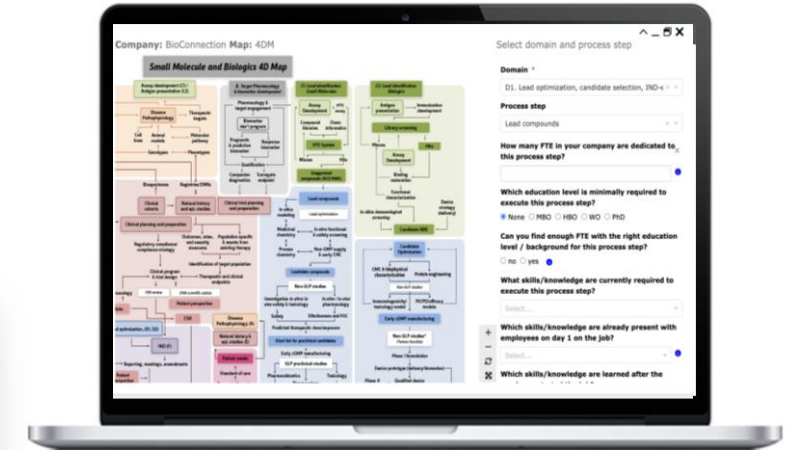
Questionnaire

Sustainable gap-analysis tool



How many FTE in your company are dedicated to this process step?	# FTE
Which education level is minimally required to execute this process step?	None MBO HBO WO PhD
Can you find sufficient FTE with the right education level / background for the process step?	
What skills/knowledge are currently required to execute this process step / domain?	Mention the competencies
What skills/knowledge are already present with employees on day 1 on the job?	Mention the competencies
What skills/knowledge are learned after the employee started the job? (=additional skills/knowledge)	Mention the competencies
Which required skills/knowledge are currently not present/learned?	Mention the competencies
How do employees mostly learn additional skills/knowledge required for this domain/process step?	On the job Internal training program External training program

HCG



Does the company currently have the necessary future-proof infrastructure to execute this process step?

- Buildings/Space
- Machines/Equipment
- Software/Models
- Certification/IP
- (Clinical) Material/Libraries

YES - NO
YES - NO
YES - NO
YES - NO
YES - NO

Per type of infrastructure, answer the following questions:

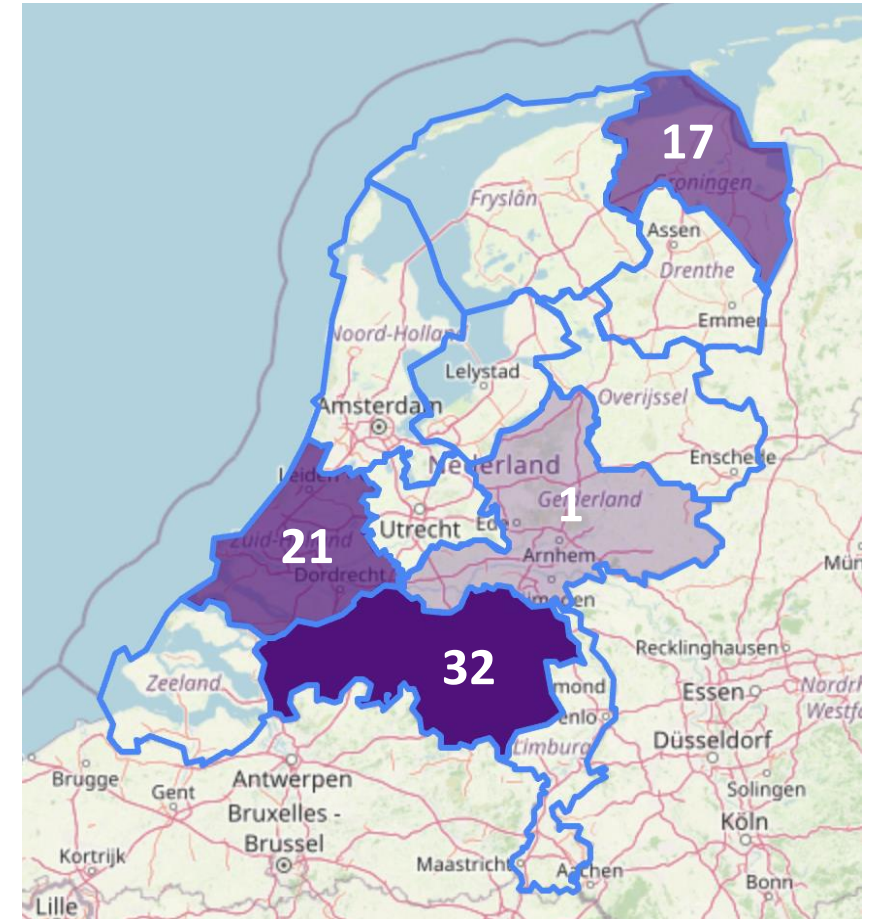
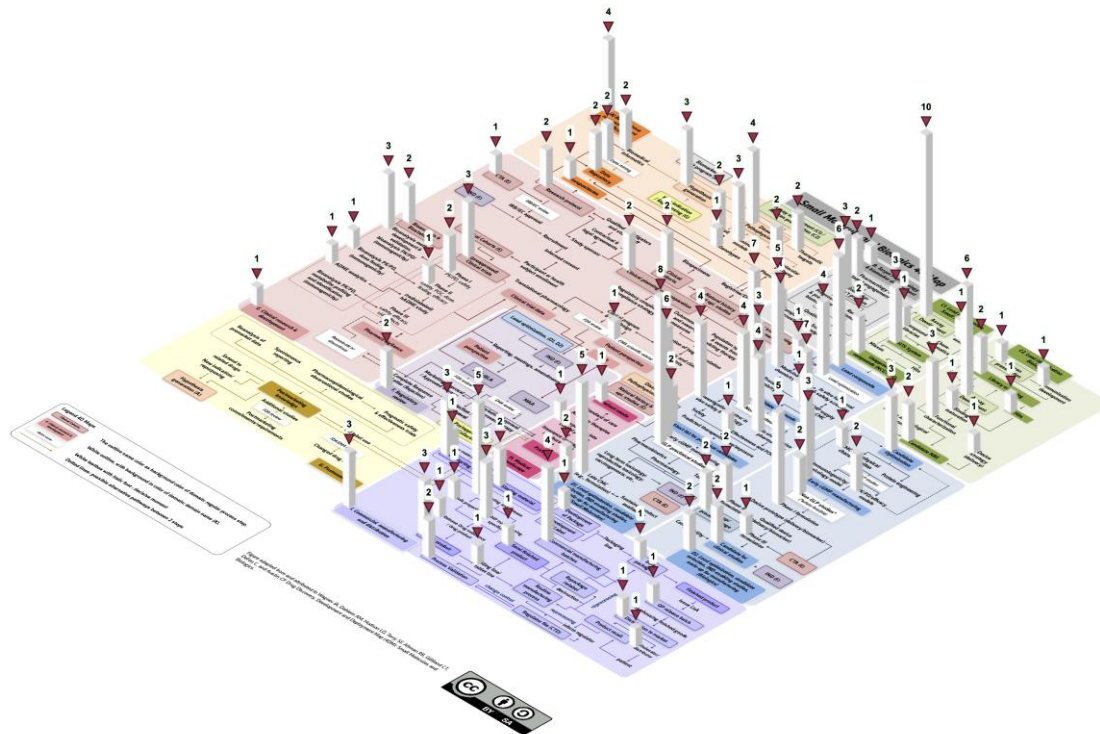
- What infrastructure is currently present in your organization?
- What infrastructure are you willing to share with other companies?
- What infrastructure would you need?

SDI



Sample size : organisations interviewed

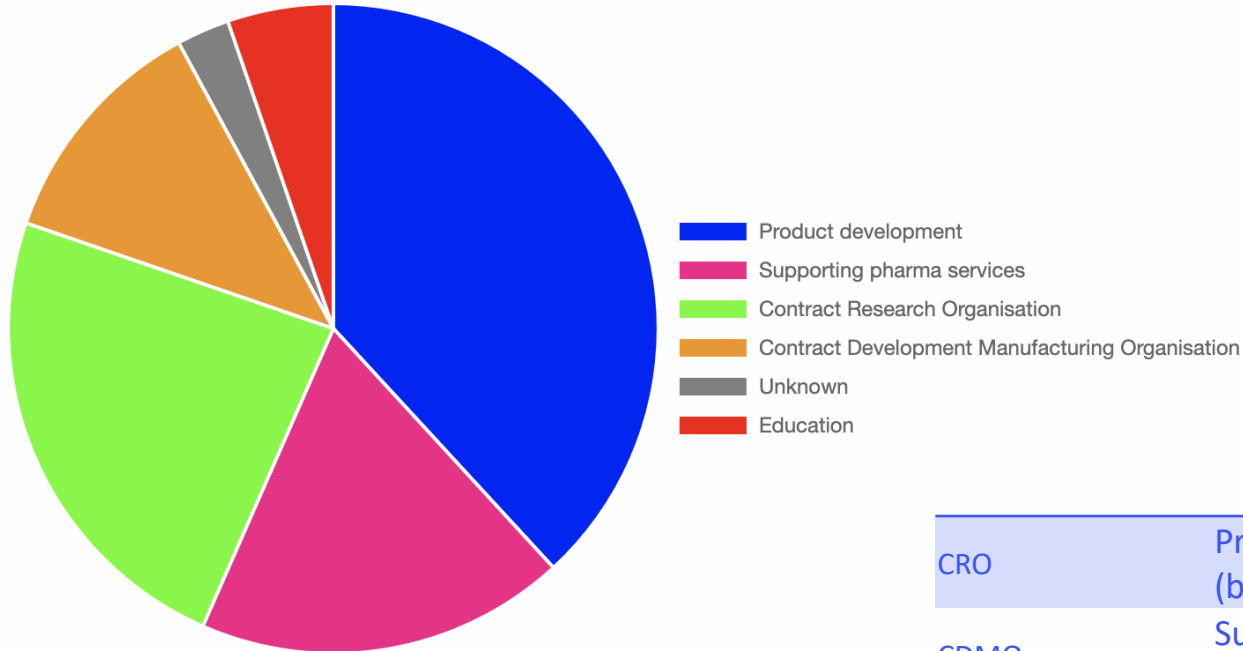
- Current sample : 71 organisations*
- 2023/24 Groningen / Campus Groningen, Leiden / Leiden BioScience Park and Pivot Park.
- From 2024 adding other pharmaceutical hubs



71 organisations interviewed*

*status May 17, 2024

Types of organisations interviewed



CRO	Provide direct support to pharmaceutical and biotechnology organizations (both preclinical and lab services and clinical trial services)
CDMO	Support pharmaceutical and biotechnology organizations with formulation and production of the developed products
PRODUCT DEVELOPMENT	Institutions, pharmaceutical and biotechnological organizations developing a therapeutic product
EDUCATION	Educational institutions (universities, HBO, MBO)
SUPPORTING PHARMA SERVICES	Provide indirect support to pharmaceutical and biotechnology organizations, e.g. recruitment and legal services.

Data management

Standardized method of documenting current and required infrastructure & skills

Name	#	Added from
<input type="checkbox"/> Cell Imaging High content imaging	44	4DMSurvey
<input type="checkbox"/> NMR	27	4DMSurvey
<input type="checkbox"/> Microscope	26	4DMSurvey
<input type="checkbox"/> HPLC Chromatography	25	4DMSurvey
<input type="checkbox"/> Mass Spectrometry	24	4DMSurvey
<input type="checkbox"/> Turbulent injection system	24	4DMSurvey
<input type="checkbox"/> Cell culture equipment	23	4DMSurvey
<input type="checkbox"/> Flow Cytometry	23	4DMSurvey
<input type="checkbox"/> PCR qPCR (quantitative real-time PCR)	23	4DMSurvey
<input type="checkbox"/> Cabinets & Cleanrooms Laminar Airflow Cabinet	22	4DMSurvey
<input type="checkbox"/> Microscope Confocal Fluorescence Microscope	22	4DMSurvey
<input type="checkbox"/> Microscope Scanning Electron Microscope	22	4DMSurvey
<input type="checkbox"/> Software & Hardware Shared IT Server environment	21	4DMSurvey
<input type="checkbox"/> Incubator CO2 incubator	18	4DMSurvey
<input type="checkbox"/> Liquid Chromatography Mass Spectrometry (LC - MS)	18	4DMSurvey
<input type="checkbox"/> Software & Hardware GraphPAD software	17	4DMSurvey
<input type="checkbox"/> Microscope Infrared microscope	15	4DMSurvey
<input type="checkbox"/> Rheometer	15	4DMSurvey
<input type="checkbox"/> Basic laboratory equipment	14	4DMSurvey
<input type="checkbox"/> Fourier Transform Infra Red Spectrometer	14	4DMSurvey
<input type="checkbox"/> Microplate reader EnVision	14	4DMSurvey
<input type="checkbox"/> Milling Nano mill	14	4DMSurvey
<input type="checkbox"/> Software & Hardware 3D printer	14	4DMSurvey
<input type="checkbox"/> Software & Hardware Modelling software	14	4DMSurvey
<input type="checkbox"/> Ultra Performance Liquid Chromatography UPLC	14	4DMSurvey
<input type="checkbox"/> Mass Spectrometry Accelerator Mass Spectrometry (AMS)	13	4DMSurvey
<input type="checkbox"/> Microscope Optical microscope	13	4DMSurvey
<input type="checkbox"/> modular manufacturing process or scalable and automated instrum...	13	4DMSurvey
<input type="checkbox"/> open source	13	4DMSurvey
<input type="checkbox"/> Cell Imaging	12	4DMSurvey
<input type="checkbox"/> Flow Cytometry iQue 3 Advanced	12	4DMSurvey
<input type="checkbox"/> Flow Sorter	12	4DMSurvey
<input type="checkbox"/> Refrigerators & Freezers Freezer -80	12	4DMSurvey

infrastructure

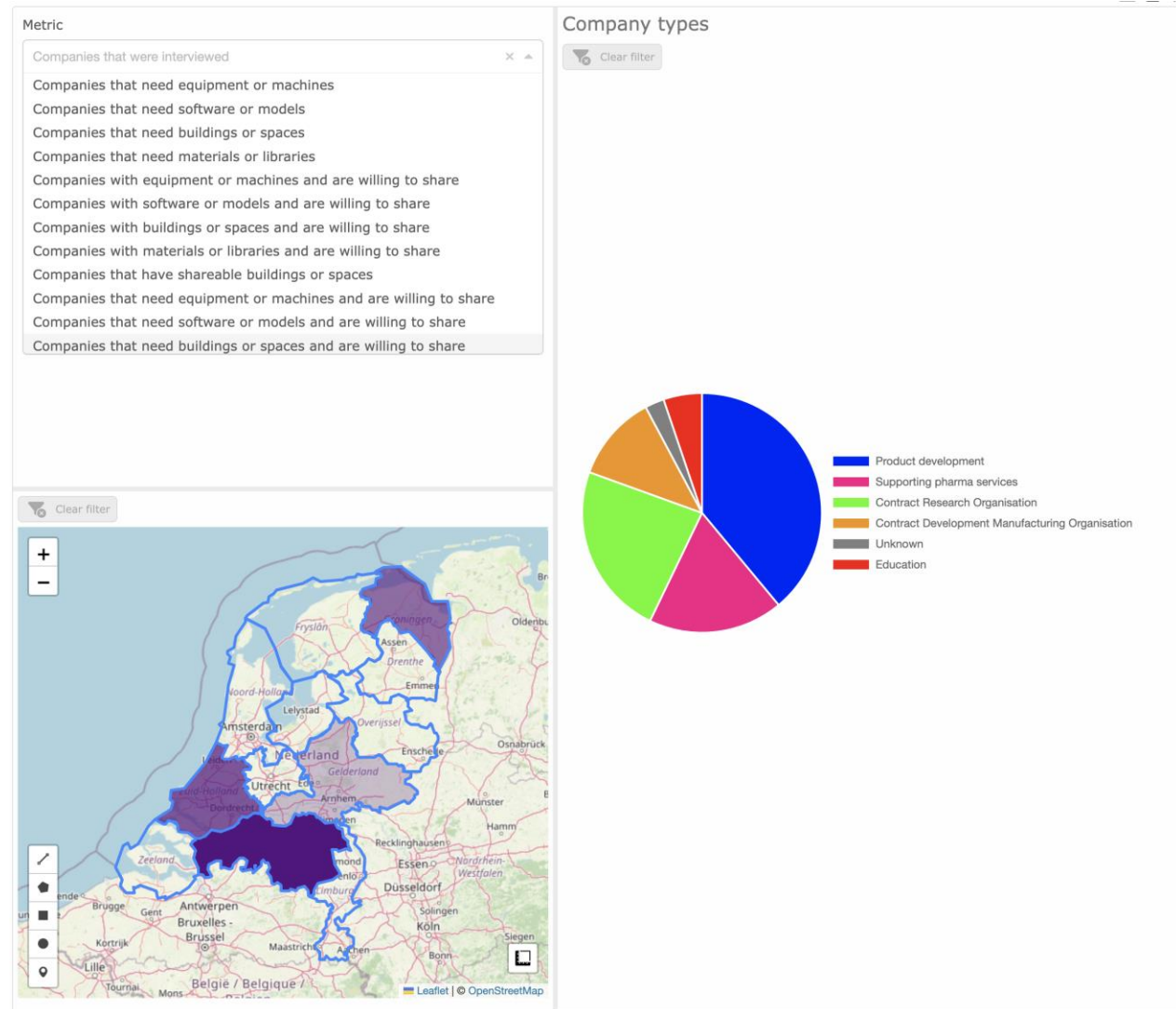
Name	#	Added from
<input type="checkbox"/> Communication skills	304	
<input type="checkbox"/> Lab skills	239	4DMSurvey
<input type="checkbox"/> Lab skills Laboratory safety skills	228	4DMSurvey
<input type="checkbox"/> Lab skills Laboratory notebooks and documentation	189	
<input type="checkbox"/> Lab skills Cell biology techniques	159	
<input type="checkbox"/> Project management skills	158	
<input type="checkbox"/> Collaboration skills	126	4DMSurvey
<input type="checkbox"/> Chemical knowledge Medicinal chemistry	115	4DMSurvey
<input type="checkbox"/> Procedures Standard Operating Procedures (SOP)	105	4DMSurvey
<input type="checkbox"/> Communication skills Reporting	104	4DMSurvey
<input type="checkbox"/> Lab skills Nucleic acid techniques	104	
<input type="checkbox"/> Lab skills Protein techniques	104	
<input type="checkbox"/> Procedures Good Manufacturing Practices (GMP)	104	
<input type="checkbox"/> Analytical thinking	102	4DMSurvey
<input type="checkbox"/> Chemical knowledge Basic	100	4DMSurvey
<input type="checkbox"/> Chemical knowledge Synthetic and structural chemistry	99	4DMSurvey
<input type="checkbox"/> Communication skills Client	99	4DMSurvey
<input type="checkbox"/> Assay development	97	
<input type="checkbox"/> Chemical knowledge Biochemical	97	4DMSurvey
<input type="checkbox"/> Data Complex data analysis	97	4DMSurvey
<input type="checkbox"/> Planning and organisation skills	96	
<input type="checkbox"/> Writing skills Technical	95	4DMSurvey
<input type="checkbox"/> Lab skills Separation techniques	93	
<input type="checkbox"/> Timemanagement	82	4DMSurvey
<input type="checkbox"/> Analysis Analytical Development	81	4DMSurvey
<input type="checkbox"/> Lab skills Microbiology techniques	75	
<input type="checkbox"/> Chemical knowledge Analytical chemistry	69	4DMSurvey
<input type="checkbox"/> Legal issues and ethics Intellectual property	69	
<input type="checkbox"/> Data Data analysis	67	4DMSurvey
<input type="checkbox"/> Patent Drafting	66	4DMSurvey
<input type="checkbox"/> Drug Development	65	4DMSurvey
<input type="checkbox"/> Advocacy	64	4DMSurvey
<input type="checkbox"/> Patent Litigation	64	4DMSurvey

skills

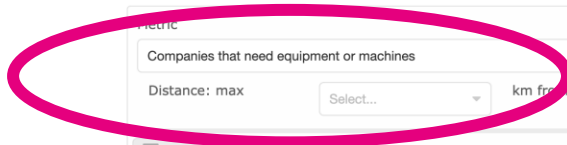


PharmaNL | infrastructure

Data dashboard - SDI



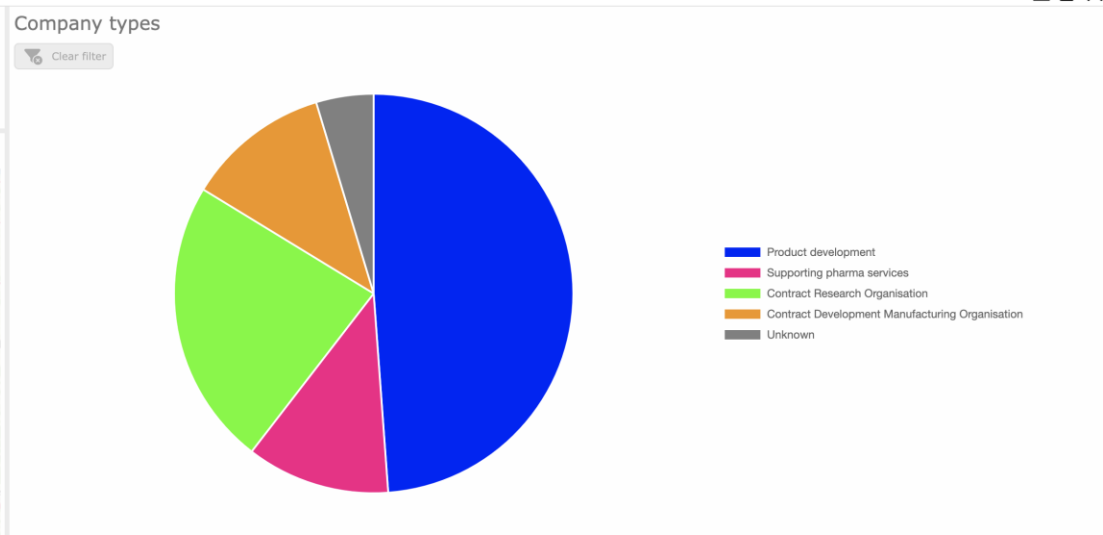
Dashboard - SDI



Search filter: Companies that need equipment or machines

Distance: max km from ZIP code

Map of Europe showing highlighted regions in the Netherlands and Germany.



Equipment / machines needed (# companies)

Description	#
Mass Spectrometry	9
Microscope	9
NMR	9
Cabinets & Cleanrooms	7
Flow Cytometry	6
Cell Imaging	5
HPLC Chromatography	5
Liquid Chromatography Mass Spectrometry (LC - MS)	5
Bioreactor	4
Centrifuge	4
Refrigerators & Freezers	4

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Companies and the equipment or machines they need

Company	Description
0c56835b-f69b-4e85-a986-27a99b53e728	Tube sorter
0e7d7a43-22e7-4bdf-9f97-f911d31fb0bb	microFLUX - Pion , evaporative light scattering detector (ELSD) , charged aerosol detector (CAD)
184b4264-4a1e-4675-b50f-54af5263197e	Reactor heater / cooler Huber , Rotary Evaporator Rotavap , Chemical reactor 50L , Cabinets & Cleanrooms Fumehood cabinets , Stirrer , Mass Spectrometry High Resolution , NMR Liquid State NMR 800 Mhz
2257be39-7f3d-4fbc-933d-9352ee3bf40	Flow Cytometry , Bioreactor Biostat A , nano assembler (GMP compatible) , Microscope Scanning Electron Microscope
2eceb4a8-f43f-4b07-9def-7fb40a6309b1	Machine DNA/mRNA production , Machine bulk packaging mRNA , Cabinets & Cleanrooms Fumehood cabinets , Microscope Confocal Fluorescence Microscope , HPLC Chromatography , Gas Chromatography Mass Spectrometry (GC - MS) , Liquid Chromatography Mass Spectrometry (LC - MS) , NMR , Flow Cytometry
36e6ae4f-fd7b-451c-b78e-d0f3d7aec448	Computer tomograph , Machines simulating transportation of product , NMR , Nanoflow size , Spectrometry ICP Analysis
3b33539e-3def-421d-a226-f89697c1cf7	Software & Hardware Mesoscale discovery software
3c5d5148-b8cc-42b2-bdfb-77f770acf519	Mass Spectrometry High Resolution , NMR

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Towards sustainable discovery and production of new therapies

Trend?	yes
In scope of other growthfund project like Biotech Booster, Oncode Accelerator, RegMedXB, CPBT?	no
Substantiated by GAP analysis?	HCG & SDI
Already part of a PharmaNL project?	Possibly
Which domains?	A, B, C, D, E, I
Programme line	HCG & SDI

Early discovery
infrastructure

HCG: #assay development #AI #robotics #automated lab
SDI: NMR, High content /Cell imaging, HTS, Flow cytometry, Microscope, SEM, Mass Spectrometry, HPLC/LC-MS/UPLC/GC-MS, Surface Plasmon Resonance, PCR, FACS

Shared
Development
Infrastructure

Human Capital

PharmaNL predefined criteria including those from NGF en ZonMw

Towards sustainable discovery and production of new therapies

Trend?	yes
In scope of other growthfund project like Biotech Booster, Oncode Accelerator, RegMedXB, CPBT?	no
Substantiated by GAP analysis?	HCG & SDI
Already part of a PharmaNL project?	nee
Which domains?	D, I
Programme line	HCG & SDI

Small scale
(shared)
manufacturing
facilities

HCG: # cleanroom / gowning procedure #personalized medicine #production #aseptic #GMP procedures #manufacturing #continuousmanufacturing

SDI: Small Scale GMP cleanroom, GMP (protein) production ; shared GMP cleanroom radiation regulated production facility

Shared
Development
Infrastructure

Human Capital

PharmaNL predefined criteria including those from NGF en ZonMw



PharmaNL | human capital

From skills to themes & trends

Acquired skills at start

Future skills

	MBO	HBO	WO	PhD		MBO	HBO	WO	PhD
Total skills recorded	52	156	147	68		24	114	128	37

Top 20-25 skills

Domains

I. Commercial manufacturing and distribution

B. Target Pharmacology & biomarker development

C1. Lead identification Small Molecules

(A) Basic science research & target identification

D1. Lead optimization, candidate selection, IND-enabling studies, scale-up for manufacturing (Small Molecules)

(A) Basic science research & target identification

B. Target Pharmacology & biomarker development

D1. Lead optimization, candidate selection, IND-enabling studies, scale-up for manufacturing (Small Molecules)

C2. Lead identification Biologics

E. Clinical research & development

D2. Lead optimization, candidate selection, IND-enabling studies, scale-up for manufacturing (Biologics)

C2. Lead identification Biologics

D1. Lead optimization, candidate selection, IND-enabling studies, scale-up for manufacturing (Small Molecules)

I. Commercial manufacturing and distribution

E. Clinical research & development

D2. Lead optimization, candidate selection, IND-enabling studies, scale-up for manufacturing (Biologics)

Examples required skills

AI, Production technology, Procedures, Lab skills, Complex data analysis, Automation, Organoids, Drug development, ATMPs, Various modelling, Chemical knowledge, cleanroom skills,,

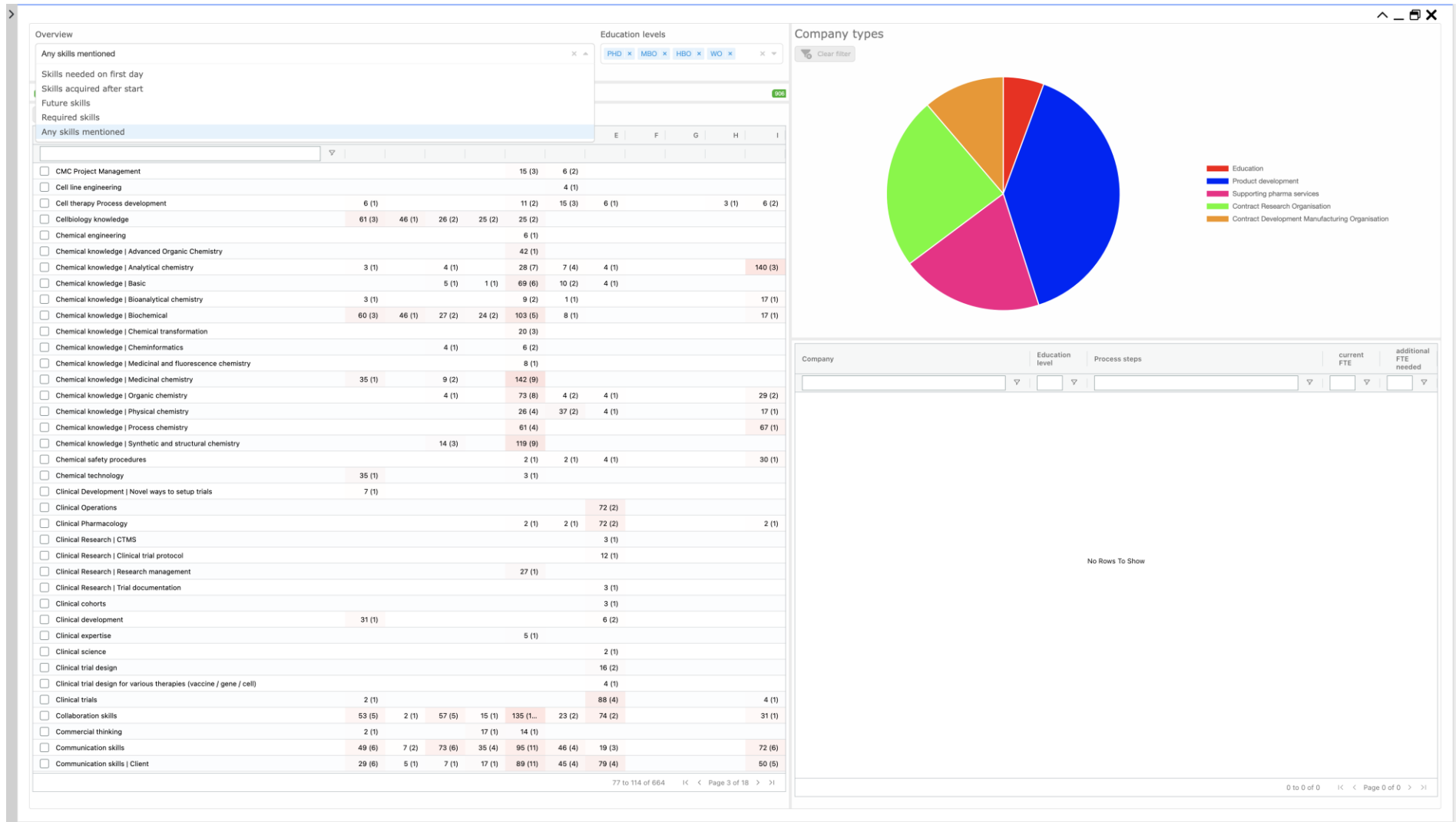
Project management, communication skills

F. Regulatory review

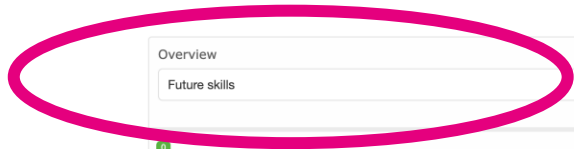
G. Postmarketing

H. Medical landscape

Heatmap- HCG



Analysis - HCG



Overview

Future skills

Education levels: WO, PHD, HBO, MBO

769

Clear filter

Skill	A	B	C1	C2	D1	D2	E	F	G	H	I
Data Complex data analysis	30 (4)	46 (1)	44 (4)	46 (3)	25 (2)	2 (1)	4 (1)				56 (1)
Artificial Intelligence	27 (3)	46 (1)	41 (3)	42 (3)	41 (4)	37 (2)	2 (1)				80 (2)
Biophysics	23 (1)	46 (1)	23 (1)	23 (1)	23 (1)						
Pharmacology	23 (1)	46 (1)	23 (1)	23 (1)	23 (1)						
data mining	25 (2)	46 (1)	23 (1)	23 (1)	23 (1)						
Mass spectrometry Skills			11 (2)								
Assay development in Drug Discovery			9 (1)								
Drug Development	31 (1)		9 (1)			150 (1)					
Mass spectrometry Knowledge			9 (1)								
Project management skills			9 (1)								
Data Mass spectrometry data analysis			7 (1)								
Lab robotics			7 (1)								
Working with LIMS			7 (1)								
Patent Drafting 2.0			5 (1)	1 (1)	15 (1)	8 (1)	4 (1)				
Patent Litigation 2.0			5 (1)	1 (1)	15 (1)	8 (1)	4 (1)				
Chemical knowledge Cheminformatics			4 (1)		4 (1)						
Computational medicinal chemistry			4 (1)		4 (1)						
Drug Discovery knowledge			4 (1)		4 (1)						
Molecular design and informatics			4 (1)								
Organoid Organoid expertise	3 (1)		3 (1)		12 (1)						
Automation Automation knowledge			2 (1)		2 (1)	2 (1)	70 (1)				769 (4)
Confocal microscopy (NIKON)			2 (1)								
Medical chemistry - translation of target biology requirements to chemical structure			2 (1)								
cell line models (renal)			2 (1)								
cell models			2 (1)								
(post translational) knowledge of proteins	31 (1)										
ADME modeling	35 (1)										

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Some high level results

MBO trained personnel largely working in domain I (Commercial Manufacturing), somewhat in D1 and D2 (In vivo + GLP preclinical + manufacturing)

High demand for (MBO) trained operators in the coming years.

Shift in required skills for MBO educated personnel due to digitization and automation

HBO,WO and PHD educated personnel mostly working in the same process steps A, B, C, D

HBO,WO and PHD educated staff mostly working in the same teams, with different responsibilities

More interviews to be done for an inventory of requirements in domains E, F,G,H (clinical, regulatory, post marketing, medical landscape)

Towards sustainable discovery and production of new therapies

Trend?	yes
In scope of other growthfund project like Biotech Booster, Oncode Accelerator, RegMedXB, CPBT?	no
Substantiated by GAP analysis?	HCG
Already part of a PharmaNL project?	no
Which domains?	I
Programme line	HCG

Automation
production &
warehousing

HCG: MBO staff working in production / warehousing need to become more knowledgeable about automation of the production process and work differently.
SDI: Continuous production, refer to GMP cleanrooms

Shared
Development
Infrastructure

Human Capital

PharmaNL predefined criteria including those from NGF en ZonMw



Towards sustainable discovery and production of new therapies

Artificial Intelligence

Trend?	yes
In scope of other growthfund project like Biotech Booster, Oncode Accelerator, RegMedXB, CPBT?	yes: infrastructure for AI
Substantiated by GAP analysis?	HCG & SDI
Already part of a PharmaNL project?	no
Which domains?	A,B, C, D, E, I
Programme line	HCG

computational life sciences #ai #artificial intelligence

PharmaNL predefined criteria including those from NGF en ZonMw

Shared
Development
Infrastructure

Human Capital

Next steps





PharmaNL

More information?



www.pharmanl.org



info@pharmanl.org