Looking forward to serving you

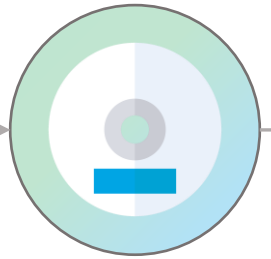
Medipha santé

Main company steps

2004

Establishment of the company with Exploitant status

2007, 2008



EuDRAcon member

eCTD software

2015

Releaser status and

Renewal of Exploitant status and WDA

Main company steps

2016

Exploitant of first product on the market

2017 - 2018

Issuance of GDP & GMP
Increase of exploitation of product

2019 - 2020

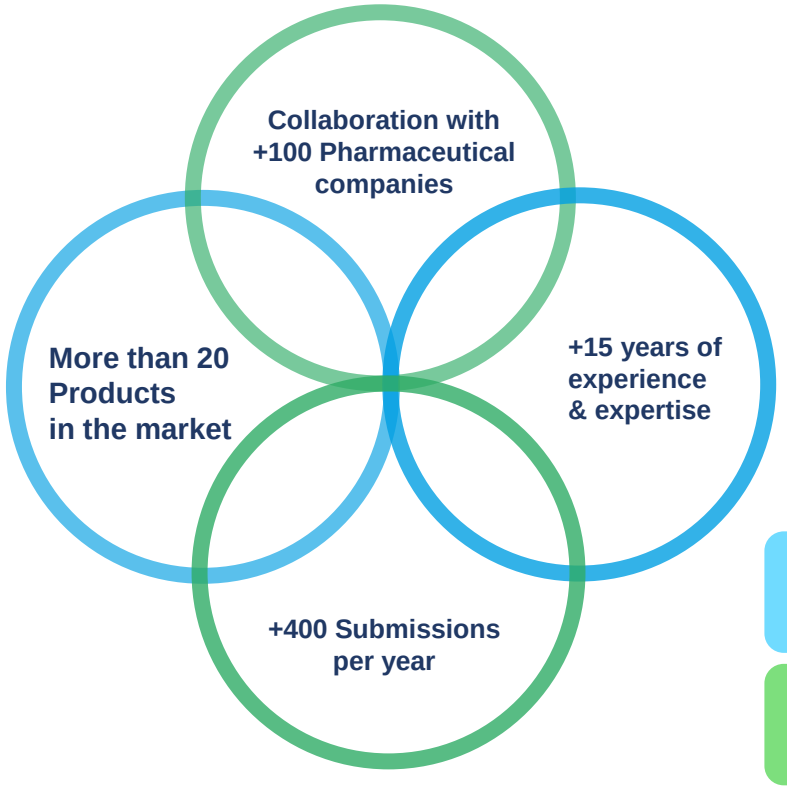
Training provider
New RA services for Export Exploitant and new Products

2021

Expansion of RA, PV, WDA activites

Our achievements

Expertise & Services



Product Portfolio

22 proprietary medicines	•19 hospital proprietary medicines •3 pharmacy proprietary medicines
8 therapeutic area	•Anaesthesia, Oncology, Cardiology, • Endocrinology , Gastroenterology, Infectiology, • Neurology, Rhumatology
6 partners	•6 manufacturers located worldwide
+2 M €	•+ 2 millions Euros generated turnover

Partnerships

French representative of European consultants network specialized in regulatory affairs

Global Regulatory Intelligence and Compliance for Human Drugs, Biologics, Medical Devices, IVDs

French generic & Biosimilar drug manufacturers' association

Medipha Santé core offerings

Regulatory Affairs services

PharmacoVigilance services

“Exploitant” and Distribution

MA Hosting, Market Access and Product Launch

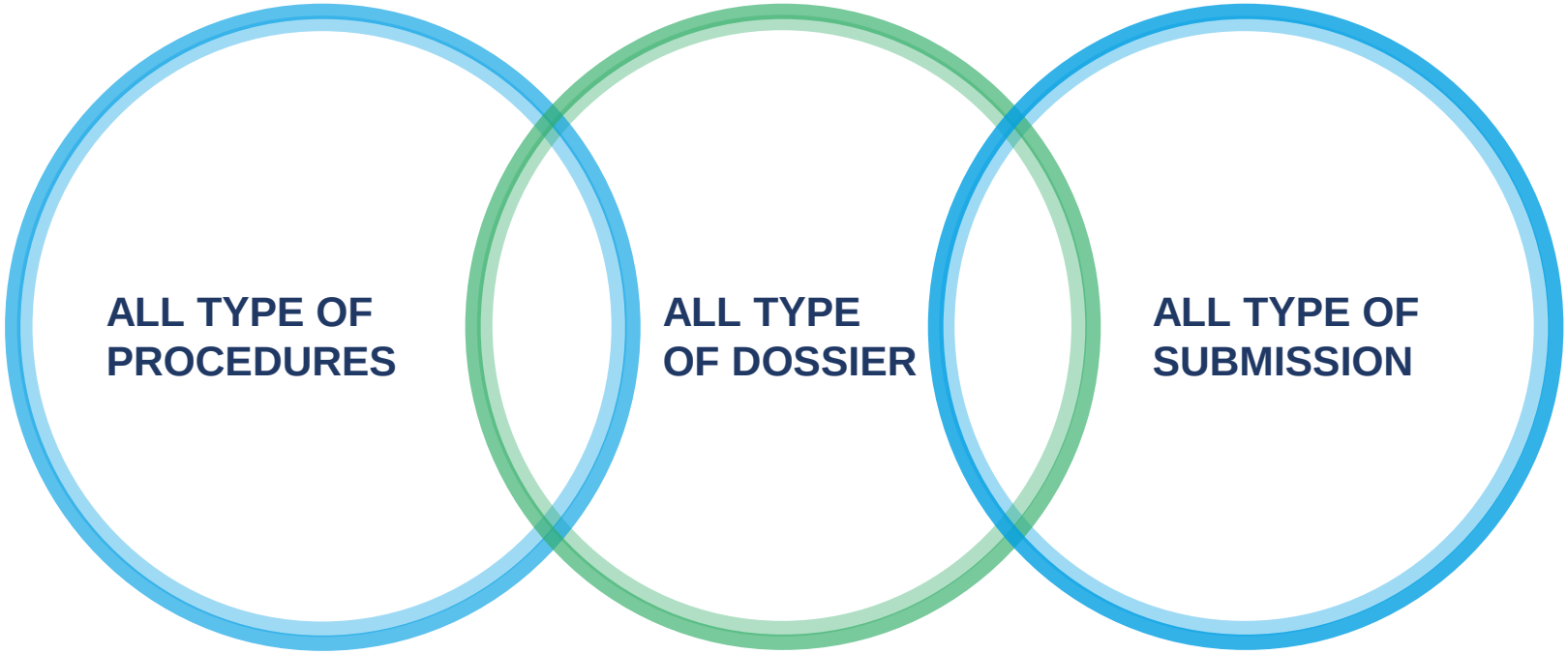
Our Expertise – the warranty to your RA

For all procedures, all along the way.

Marketing Authorisation
&
Post-marketing authorisation maintenance
(variation, renewal, Sunset clause, etc.)
&
Market Access

- **RA advices, expertise** and submissions according to Regulation of target country
- **Evaluation, Creation, redaction** and regular update of dossier according to regulation update
- **Meeting** with national Competent Authorities – communication and update of dossier for **RtQ**

Regulatory Affairs Services



- **National procedure**
- **Decentralized & Mutual Recognition procedure**
- **Centralized Procedure**
- **WHO**
- **FDA**
- **UEMOA**
- **JP**
- **…**

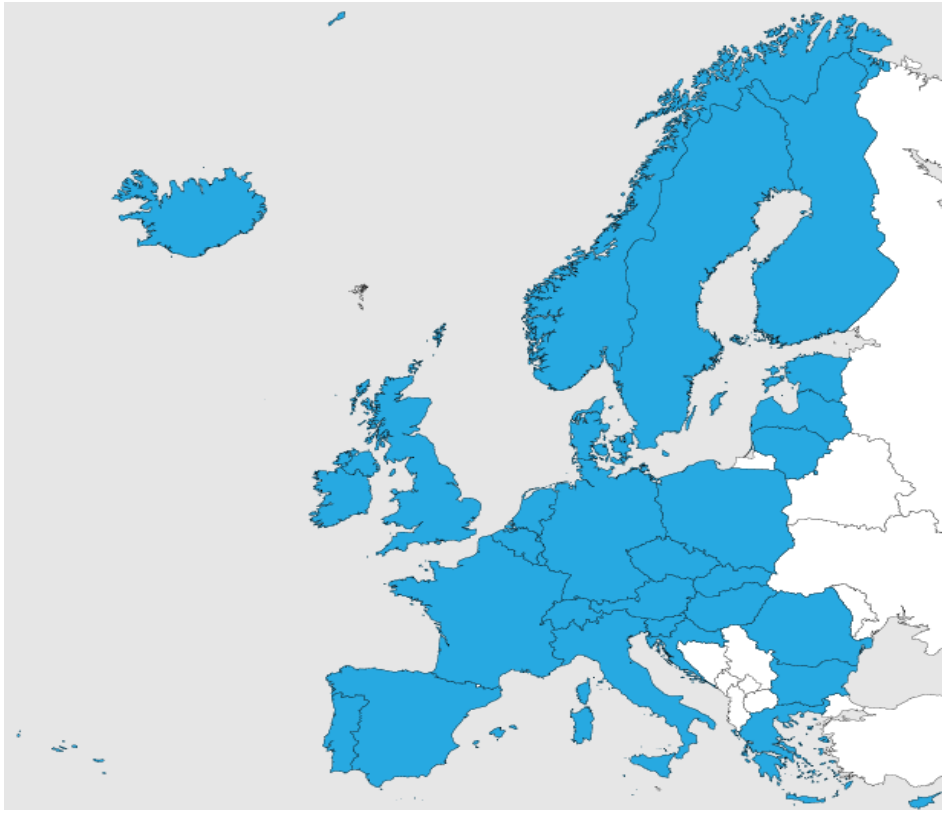
- **Abridged dossiers** (generic, hybrid, WEU, bibliographic)
- **Full dossiers**
- **Compassionate use** (ATU nominative, ATU cohort)
- **ASMF/DMF**
- **EDQM**
- **…**

- **eCTD/NeeS**
- **All types of application / all regions & countries**: EU eCTD / US /GCC/CA, JP, HR,
- **Baselines, AMM, CTA, ASMF/DMF, initial application, amendment, RtQ, variations, working documents,**
- **National Portal registration**
- **Physical submission**
- **CESSP**

Regulatory Affairs services

- **Marketing Authorization applications**
  (CP, DCP, MRP, FDA, WHO, National) human and veterinary use
- **Post-marketing authorization maintenance**
  (variations IA, IB, II, art. 61(3), renewals ,etc.)
- **Publishing / Management eCTD, NeeS**
  (All types of application / all regions & countries)
- **Compilation, Redaction of dossier**
  (AMM Module M2, M3, CEP, ASMF)
- **Regulatory strategy council**
- **ICH Compliance**
  (**Q3D** investigation repport, **Q1A** shortage management plan, etc.)
- **Pricing and Reimbursement** leading to Market Access
- **Translation** (FR/EN, full dossier, national Phase, technical documentation)
- **Audit of dossier** (M2 to M5)
- **Readability tests, mock-up production**
- **Active substance** (CEP, ASMF) submission and follow up
- **Review of promotional materials**
- **Medical device** (2017/745)
- **Clinical Trial Application**
- **Trainings** (eCTD, NeeS, etc.)
- **Outside EU** (expertise i.e. African regulations, export, CPP, etc.)

European presence and expertise



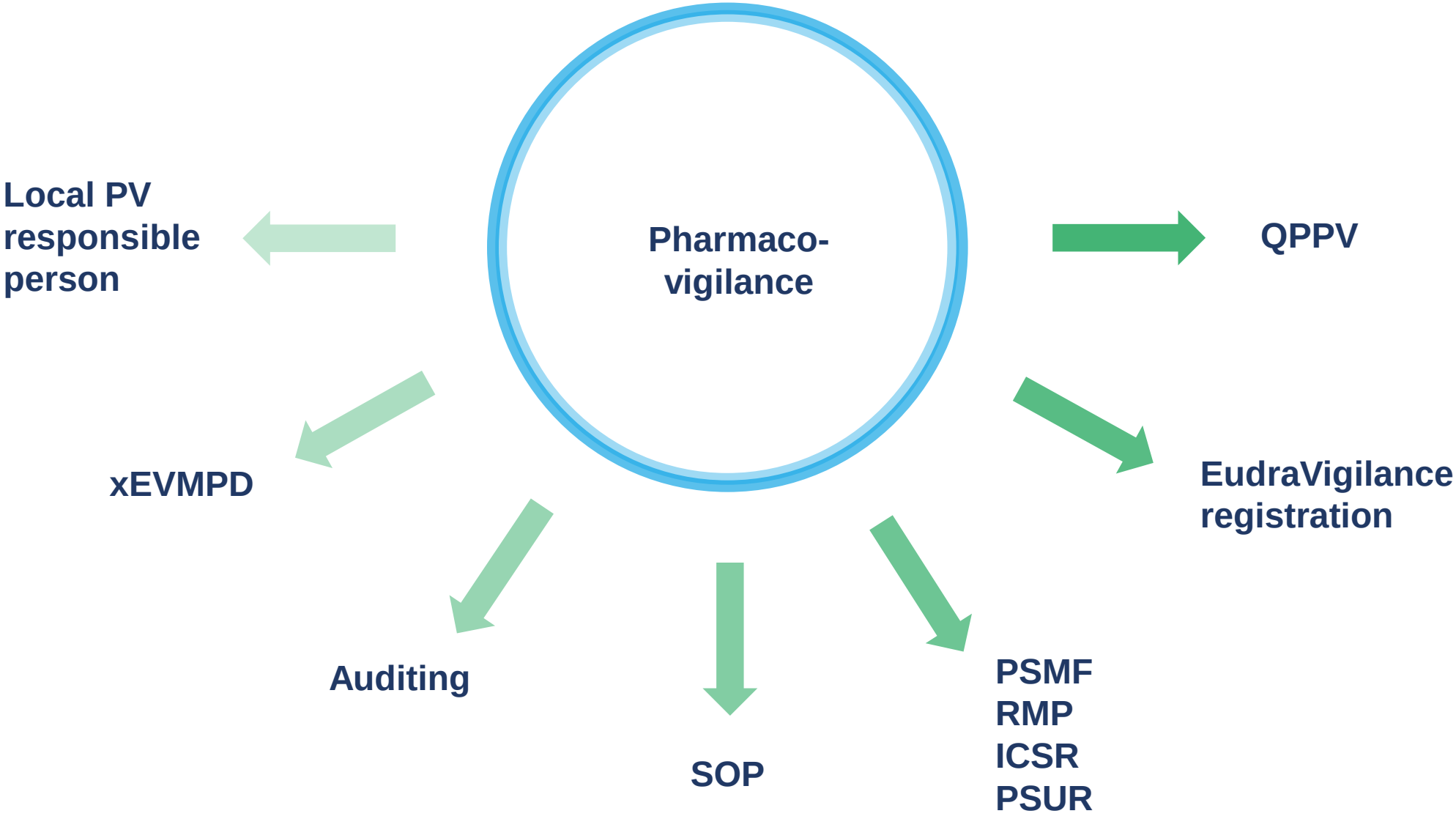
- The EuDRAcon network presently covers the following countries:
- Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, and the UK.
- EuDRAcon is a developing network pursuing to fill the vacancies for those EU member states not yet included in the list.

Worldwide Regulatory Intelligence and Expertise

Tarius currently includes the following countries, regions, organizations and standards – with more to come:

- **North and South America:** Argentina, Brazil, Canada, Chile, Colombia, Costa Rica, Ecuador, Guatemala, Mexico, Panama, Peru, Puerto Rico, USA and Venezuela.
- **EU And EU Member States:** European Union, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden and United Kingdom.
- **European non-EU countries:** Albania, Bosnia-Herzegovina, Iceland, Kosovo, Macedonia, Montenegro, Norway, Serbia and Switzerland.
- **CIS (Commonwealth of Independent States):** Belarus, Kazakhstan, Russia and Ukraine
- **Middle East:** Algeria, Bahrain, Egypt, Iraq, Israel, Jordan, Kuwait, Lebanon, Morocco, Oman, Qatar, Saudi Arabia, Tunisia, Turkey and United Arab Emirates.
- **Africa:** Kenya, Nigeria and South Africa.
- **Asia and the Pacific:** Australia, China, Hong Kong, India, Indonesia, Japan, Malaysia, New Zealand, Philippines, Singapore, South Korea, Sri Lanka, Taiwan, Thailand and Vietnam.
- **Organizations and Standards:** AHWP, ANZTPA, ASEAN, CIOMS, EAEU, EDMA, EFPIA, Eucomed, GCC, GHTF/IMDRF, ICH, ISO, League of Arab States, MedTech Europe, MERCOSUR, OECD, PIC/S, US ASTM, WHO and WMA

Pharmacovigilance Services



« Exploitant » and distribution

- RA monitoring & maintenance
- Sunset clause
- Promotion
- Advertising control
- Pricing & Reimbursement application

- Local PV responsible person
- Local literature monitoring
- Handling of ICSR
- Medical information

- QA control
- Handling quality complaints
- Distribution/wholesale
- Mock-up approval
- Quality Assurance Audits

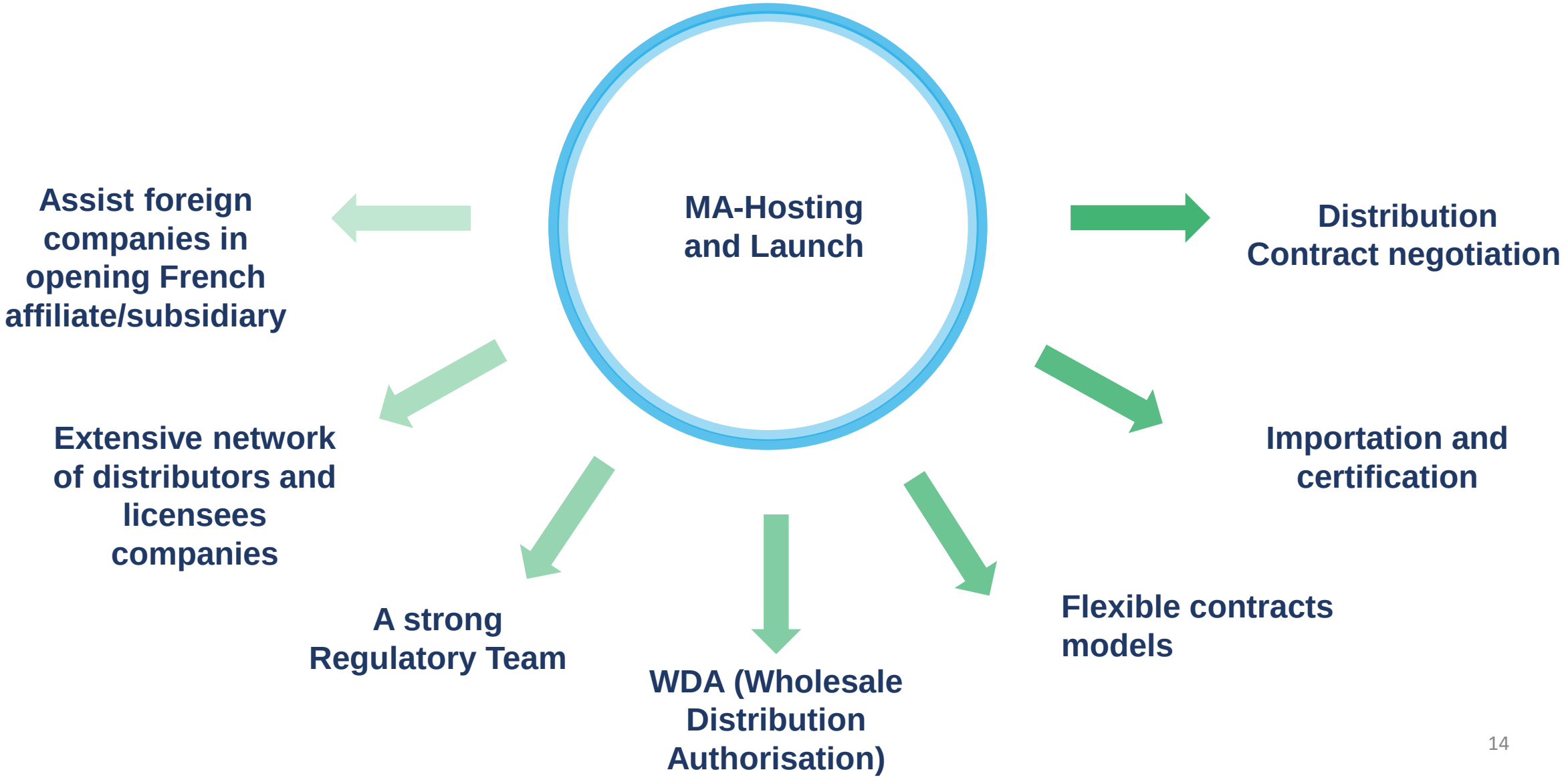
« Exploitant » and distribution

”Exploitant ” is a company or organization responsible for the “exploitation”, i.e. commercialisation of the product in French market.

The ”exploitation” activities include but are not limited to :

- **Pharmacovigilance**
- **Information**
- **Batch follow-up**
- **Batch recall if required**
- **Advertising**
- **Wholesale and distribution of operated products**
- **Importation operations**
- **Product storage operations**

MA Hosting, Market Access and Product Launch



About us

Medipha Santé, “exploitant” and importer was set-up in 2004 and as a French pharmaceutical company, offers you a wide range of health-related services (medicinal products for human or veterinary use, medical devices.

For almost 15 years, Medipha Santé has served more than forty customers worldwide and has submitted around 350 MA dossiers to the European competent authorities (ANSM, EMA,…) and markets, for third persons, a dozen of proprietary medicinal products in France (cities and hospitals).

Due to our experience, status and structure, we are able to provide you with swift and confidential expertise and assistance.

Commercial, Marketing and Business Development

Luc LAMIRAULT
CEO

Karima HEBBACHE
Project Manager

Eduardo RODRIGUEZ
Responsible Logistics

Claudia GROHMANN
BD and legal expert

Alban JADOT
Business Development

Pharmacovigilance Team

Kevin BONDIGUEL
Responsible Pharmacist
EU QPPV

Matthieu CHOPIN
Manager PV

Pauline TOTI
PV Officer

Mariam SAWADOGO
QA, PV Pharmacist

Jennifer ROTA
QA, PV Pharmacist

Yves LIORZOU
Deputy Responsible Pharmacist

Quality Assurance Team

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Responsible Pharmacist EU QPPV

Annie-Lucie MOIGNET
Quality Assurance Director

Yves LIORZOU
Deputy Responsible Pharmacist

Mariam SAWADOGO
QA, PV Pharmacist

Jennifer ROTA
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Katia NAIT AMER
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RA Officer

Ingrid NANA
RA Officer

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Christine FRANCOIS
Assistante for Commercial and Administration

Claudia GROHMANN
legal expert and BD

Julie DAUDE
Accountant Assistant

Looking forward to serving you