Looking forward to serving you

Medipha santé

Main company steps

2004

Birth of the company with Exploitant status

2007, 2008

EuDRAcon member

eCTD software

2013

Renewal of Exploitant status

Main company steps

2015

Releaser status and

Renewal of Exploitant status

2016

Exploitant of KOLBAM

2017

Exploitant of FIBROVEIN

Launch of products under preparation

Our achievements

Excellent Expertises & Services

Partnerships

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

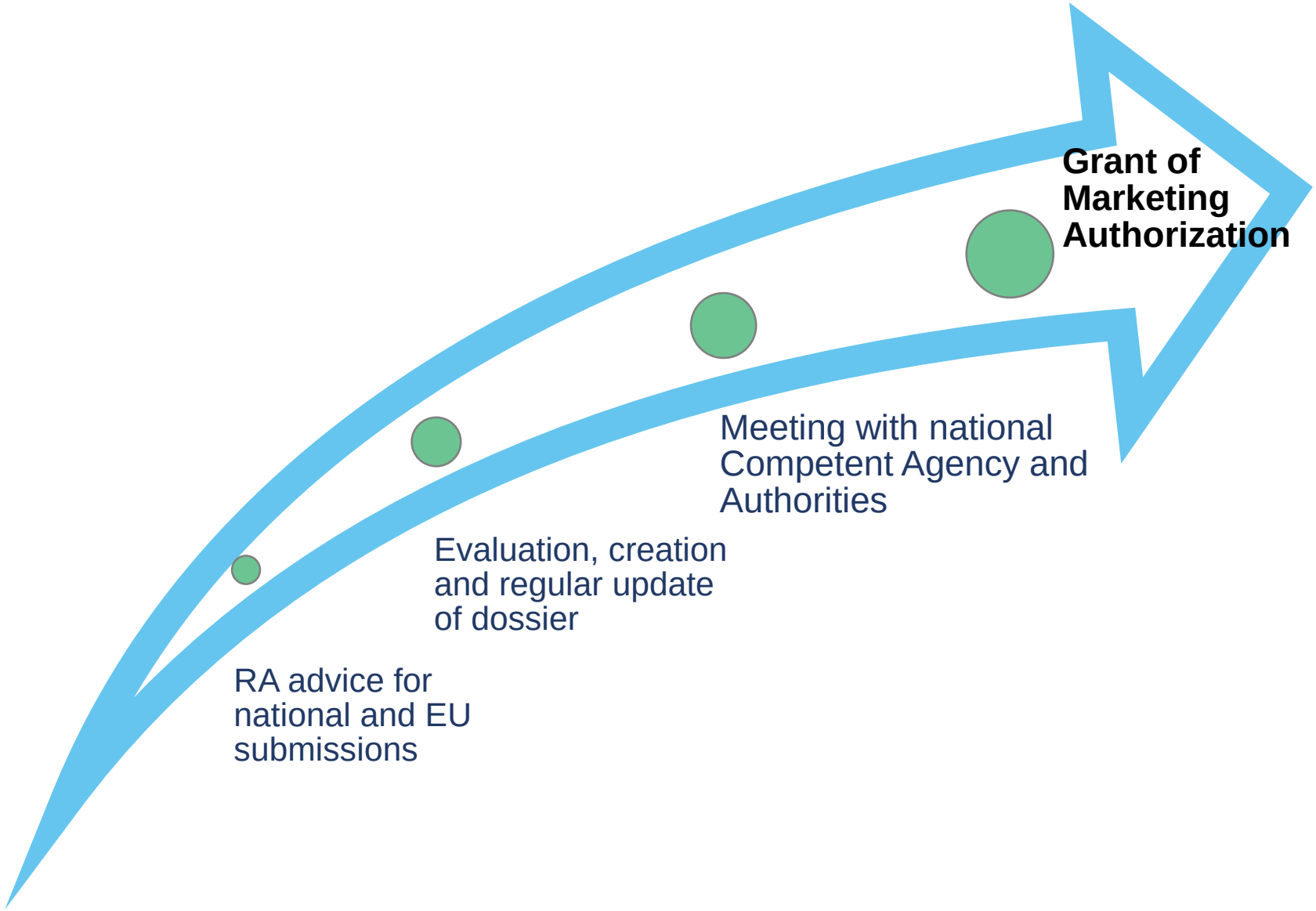
Regulatory Affairs services

PharmacoVigilance services

“Exploitant” and Distribution

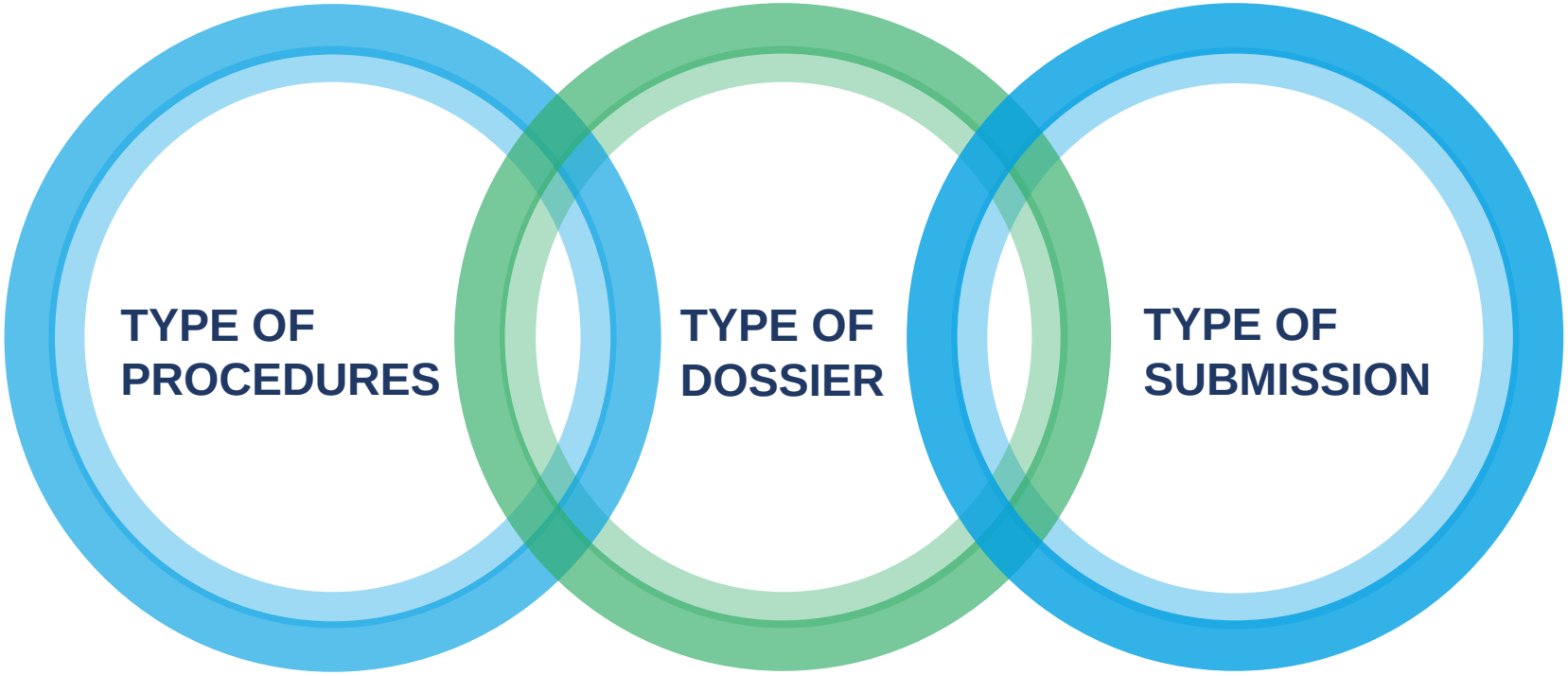
MA Hosting, Market Access and Product Launch

Our Expertise – your warranty to the MA of your product



Post-marketing authorization maintenance & Market Access

Regulatory Affairs services



- Decentralized procedure
- National procedure
- Centralized procedure
- WHO
- FDA

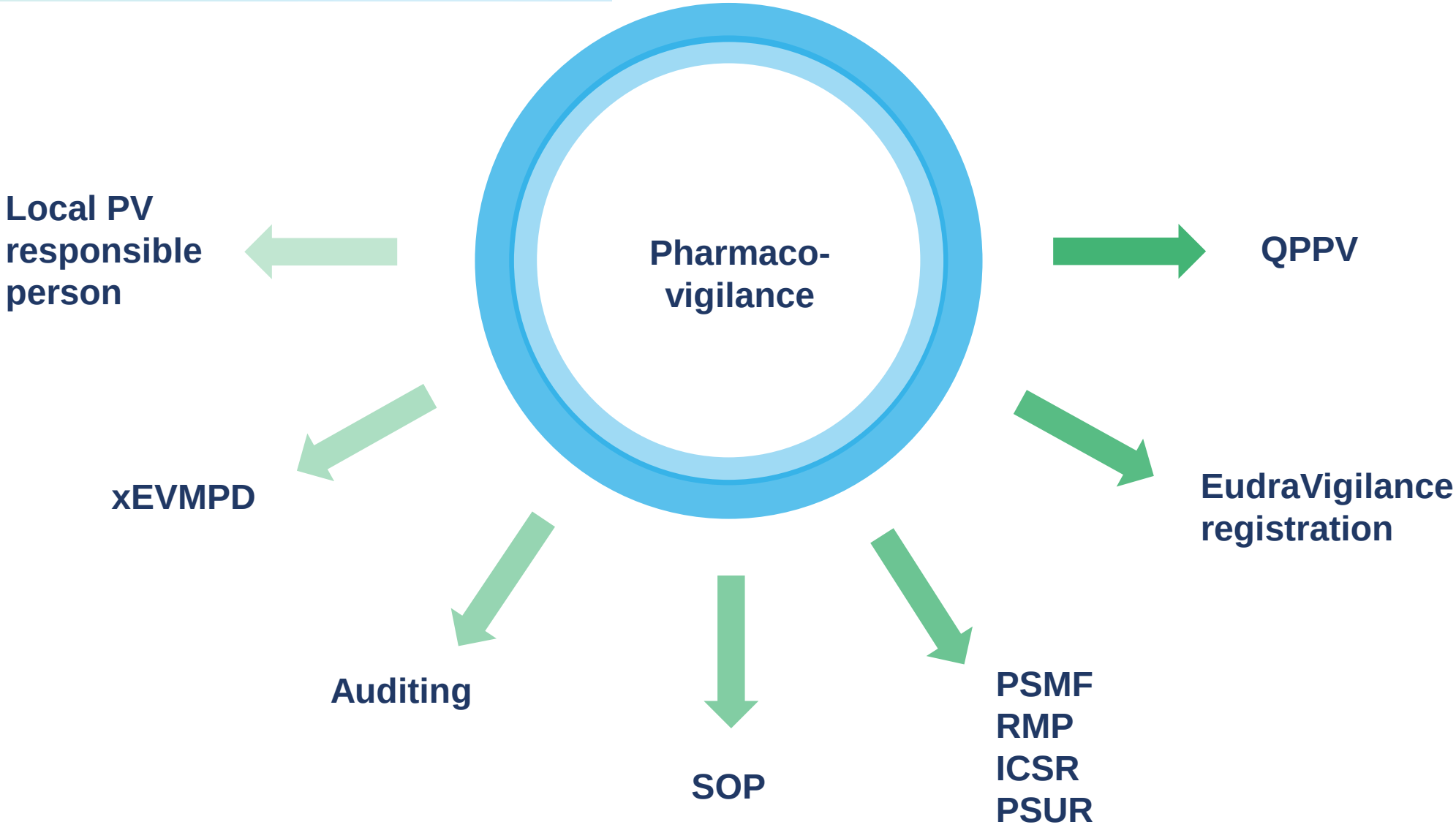
- All types of application / all regions & countries: EU eCTD / US – eCTD / GCC eCTD / CA, JP, HR,
- Baselines, AMM, CTA, ASMF/DMF, initial application, amendment, RtQ, variations, working documents,
- eCTD/NeeS
- National Portal registration
- Physical submission
- CESSP

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

Regulatory Affairs services

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

Pharmacovigilance Services



Pharmacovigilance Services

- Provision of local QPPV (local Qualified Person in Pharmacovigilance)
- Local literature monitoring related to Pharmacovigilance
- Coding of adverse events by MedDRA
- Assessment according to the French official method (Begaud)
- Preparation of safety reports for submission to Sponsors, Regulatory Authorities, Ethics Committees, IRBs and Investigators
- Electronic database (EVEreport)
- ICSR Submissions to Eudravigilance
- Knowledge of European PV legislation and guidance
- Pharmacovigilance assistance 24/7
- Risk Management Plan (RMP), preparation and maintenance
- PSMF – Pharmacovigilance System Master File
- PV-training

« Exploitant » and distribution

- 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

Assist foreign companies in opening French affiliate/subsidiary

Distribution Contract negotiation

Extensive network of distributors and licensees companies

Importation and certification

A strong Regulatory Team

WDA (Wholesale Distribution Authorisation)

Flexible contracts models

MA Hosting, Market Access and Product Launch

- **Market analysis**
- **Prices and Sales strategy**
- **Market Access**
- **Launch**
- **Preparation and Co-ordination**
- **Promotion**
- **Supply and TA with pre-wholesaler**
- **GDP knowledge**

Agency and Broker Activities

- **In-licensing & out-licensing of product portfolio, leveraging authorized business**
  - **Locate products for in-licensing according to client’s specified requirements**
  - **Identify potential licensees for clients' own products**
  - **Attractive product list**

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.

Administrative and BD Team

Luc LAMIRAULT
CEO

Karima HEBBACHE
Project Manager

Claudia GROHMANN
Commercial Assistant

Muriel AMIECH
Responsible for administration

Eduardo RODRIGUEZ
Responsible Logistics

PV / Quality Assurance Team

Kevin BONDIGUEL
Responsible Pharmacist
EU QPPV

Yves LIORZOU
Deputy Responsible Pharmacist

Annie-Lucie MOIGNET
Quality Assurance Director

Mariam SAWADOGO
QA, PV Officer

Jennifer ROTA
QA, PV Officer

Lamia EL BATTAT
Manager PV, QA

Regulatory Affairs Team

Maxime CHAUVEAU
Technico Regulatory Affairs Manager

Claire CHANDIOUX
RA Officer

Marwa ABBASSI
RA Officer

Ingrid NANA
RA Officer

Audrey ATIKPO
RA Officer

Brahim BOUHASSANI
RA Officer

Looking forward to serving you

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