Alexandra Carrel

MCE CARREL
AVOCATS

FROM THE LAB TO THE MARKET

MCE CARREL Paris • 67, rue de Miromesnil – F-75008 Paris • +33 1 45 63 01 59

SUMMARY

Drug development timeline

DISCOVERY | **DEVELOPMENT** | **MANUFACTURING** | **DISTRIBUTION**

Fundamental research → Pre-clinical Lead Discovery → Drug Substance (DS) → Drug Product (DP) → Clinical Supply → Commercial Supply → Marketing Sales Distribution

Associated legal documents:
- *Consulting agreements*
- *Master Service Agreements (manufacturer, CRO)*
- *Clinical Trial Agreement*
- *Insurance contract*
- *Regulatory pre-clinical and clinical advice*

A long and expensive process

It takes around ten years and up to several hundreds of millions to bring a new drug from the academic laboratory where it is discovered to the market as a cure for patients.

- Academics -> **Fundamental research up to initial proof of concept and patent**
  -> financed by public money (from 1M to 20M)
- Start-ups -> **Preclinical and clinical research up to end of Phase II clinical trial**
  -> financed by investment funds and public money (from 5M to 90M)
- Pharma -> **Phase III clinical trial up to market authorization and commercialization**
  -> auto-financed (from 20M to more than 100M)

I. CREATION OF THE START-UP

- **BUSINESS PLAN**
- **IP ASSETS**
- **TYPE OF COMPANY**
- **BY-LAWS AND SHAREHOLDERS AGREEMENT**
- **MANAGEMENT TEAM**

"***A good management may succeed with a bad idea but a bad management will ruin a good one***"

(Peter Kolchinsky, Phd The Entrepreneur's Guide to a Biotech Startup)

Associated legal documents:
- ***In-License***
- ***By-laws***
- ***Shareholders agreement***

II. FINANCING OF THE START-UP

Types of Financing

- Non-Dilutive - Public grants (government grants, funding from regional or international agencies)
- Dilutive:
  - ✓ Love Money (founders, close friends or family members)
  - ✓ Pre-seed
  - ✓ Seed
  - ✓ Serie A
  - ✓ Serie B
  - ✓ Serie C; etc.

Types of Investors

- Business angels (private individuals who invest in businesses)
- Family Office (privately held company investing funds for wealthy families)
- Public bank / funds
- Venture Capital Funds – Corporate VC

Associated legal documents:
- ***Term Sheet***
- ***Shareholder's agreement***
- ***Investment agreement***

III. DEVELOPING THE INVENTION

- **PRE-CLINICAL STAGES**
  - Discovery - Proof of concept and Development
  - Manufacturing of Product at industrial level (GLP/GMP)
  - Preclinical Research

- **CLINICAL DEVELOPMENT**
  - **Phase I**: Initial clinical trials to establish safety
  - **Phase II**: Initial clinical trials to establish efficacity
  - **Phase III**: Initial clinical trials to establish clinical benefit

- **REGULATORY AUTHORITIES' REVIEW**
  - During pre-clinical and clinical development
  - Regulatory Authorities examine all the data related to the drug or device and make a decision to approve or not to approve it.

- **POST-MARKET AUTHORIZATION (Safety Monitoring)**

  Regulatory Authorities monitor all drug and device safety once products on the market.

***Associated legal documents*:**
- ***Consulting agreements***
- ***Master Service Agreements (manufacturer, CRO)***
- ***Clinical Trial Agreement***
- ***Insurance contract***
- ***Regulatory pre-clinical and clinical advice***

IV. EXIT

- **IPO (INITIAL PUBLIC OFFERING)**

  Shareholders may use the financial markets to sell their shares in the company which becomes listed on the stock exchange.

  - Allows shareholders to find significant funds while retaining the majority of capital
  - Allows the company to gain visibility
  - Allows investors to manage the timing of their exit

- **M&A**

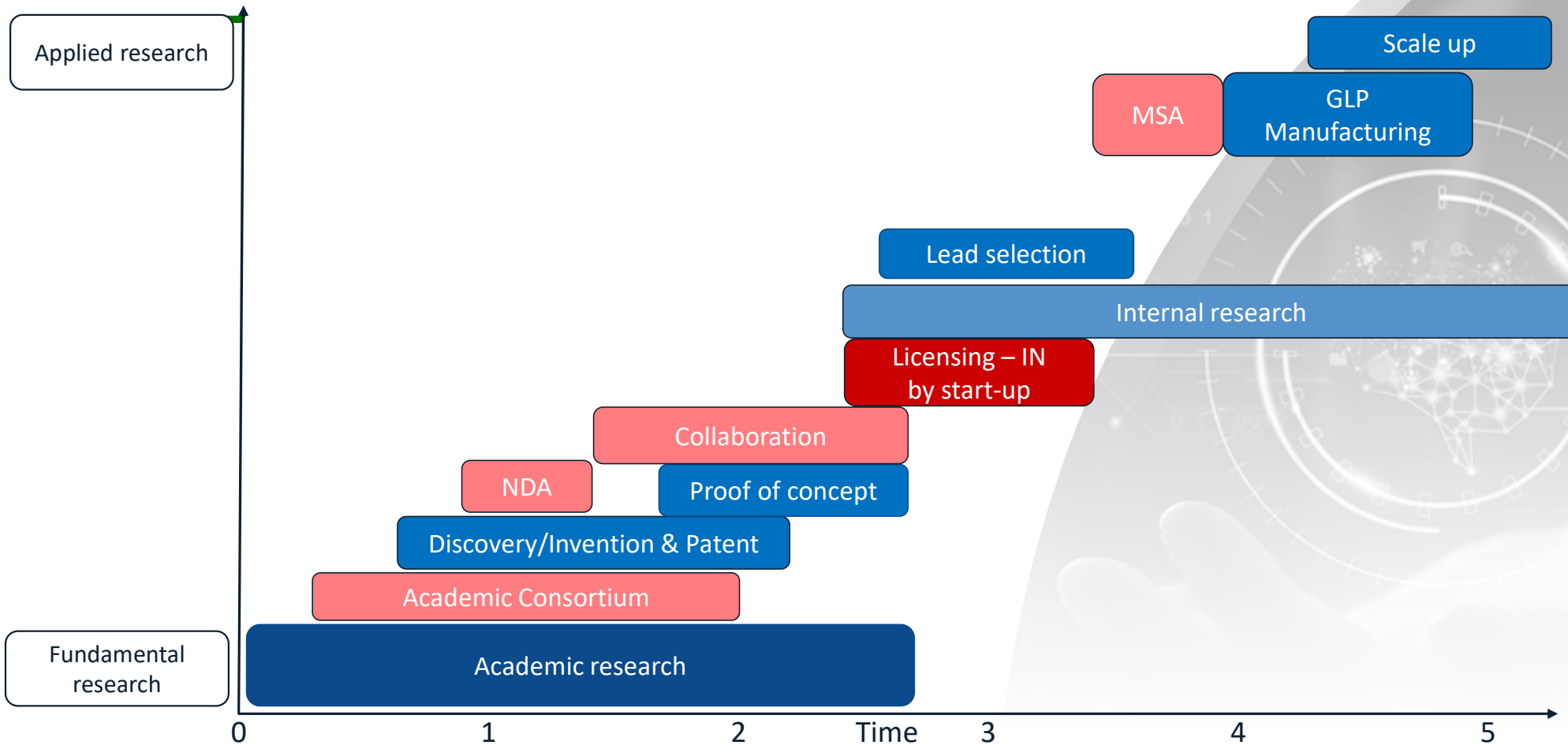
  - Directly buy the securities of the target or
  - Create a new vehicle ("newco") that will carry the target's securities

    Specific issues:
    - *Remain in the company (as minority shareholder or manager) or not?*
    - *Respect of non-competition clauses*
    - *Payment of a transformation event royalty stated in the license agreement*

- **LICENSE OR SUB-LICENSE OF EXPLOITATION RIGHTS**

  - « *A typical exit strategy is to license the development rights to a large multinational pharmaceutical company after a successful Phase I study or after proof of concept (usually in Phase II) is established.* » (Peter Kolchinsky, PhD The Entrepreneur's Guide to a Biotech Startup)

  - « *Most of the value of drug development is realized near the end of the process, when the risk of clinical failure has been mitigated with positive data. With positive Phase III data, for example, the company may be able to negotiate a deal with generous upfront.* »


Applied research
Fundamental research
Academic research
Academic Consortium
Discovery/Invention & Patent
NDA
Proof of concept
Collaboration
Licensing – IN by start-up
Internal research
Lead selection
MSA
GLP Manufacturing
Scale up
0
1
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Time
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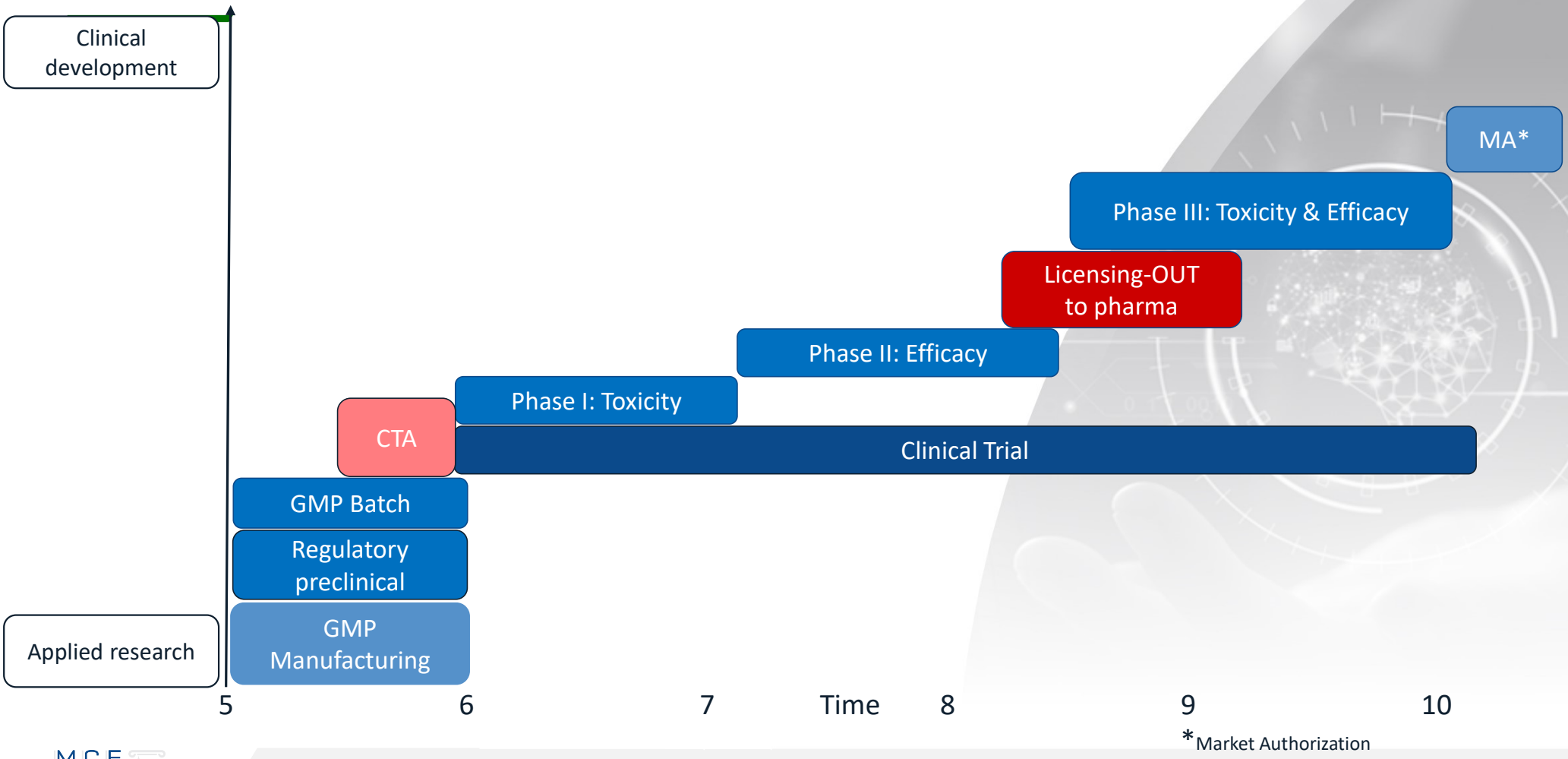

*Market Authorization

Alexandra CARREL

Biography

Alexandra Carrel is the former General Counsel and Secretary General of Inserm Transfert, TTO of Inserm, and worked for global law firms in London, Geneva, and Paris before setting up Cabinet Carrel in 2014, which became the French offices of MCE Avocats in 2021.

She is a Certified Licensing Professional and has acquired unique expertise in innovation and technology transfer, with a focus in the life sciences.

Alexandra Carrel is admitted to the Geneva (1997) and Paris Bars (2002).

Her expertise in intellectual property and business law allows her to intervene in complex operations and to assist her clients in all elements of the process from the protection of their innovations to the outsourcing of their technology, including the development, registration, manufacture, production and marketing of their products.

Recent operations

- Advice to innovative start-up companies as well as to academic institutions for the negotiation of licenses (in- and out-) and co-development agreements with industrial partners.
- Advice to biotech and medtech companies in cross-licensing agreements with industrial partners.
- Advice to innovative start-up companies on the development, manufacture, production and distribution of their new product.
- Advice to innovative start-up companies on their fundraising process.
- IP and contract audit for investors or for the target company, in view of an investment round or an acquisition.
- Advice to innovative start-up companies on the sale of their assets to industrial groups.
- Advice to start-ups regarding the negotiation of agreements with academic institutions (collaboration, co-development or lincense-in/out).

Founding partner
Admitted to Paris and Geneva Bars
Certified Licensing Professional

MCE AVOCATS lausanne
a.carrel@mcelegal.ch

MCE CARREL Paris
a.carrel@mce-carrel.fr

Contact

Alexandra CARREL
PARTNER

Tel : +33 1 45 63 01 59
a.carrel@mce-carrel.fr

NOS BUREAUX

France

MCE CARREL Paris
67, rue de Miromesnil – F-75008 Paris

MCE CARREL Lyon
16, avenue Maréchal Foch – F69006 Lyon

Suisse

MCE Lausanne
Grand-Chêne 1-3 - CH-1002 Lausanne

MCE Martigny
Av. de la Gare 56 - CH-1920 Martigny

MCE Zurich
Othmarstrasse 8 - Postfach - CH-8032 Zurich

MCE Lugano
Via Ginevra 5 - CH-6900 Lugano

Singapour

MCE Singapour
18 Robinson Road, 15-01 - Singapore 049483

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“Protecting your interests is our profession“

Thanks

MCE CARREL Paris • 67, rue de Miromesnil – F-75008 Paris • +33 1 45 63 01 59