COMMERCIALIZATION OF BIOMEDICAL RESEARCH

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Commercialization of biomedical research

- Roadmap of the process of taking a biomedical invention and creating a product that can pass the regulatory approval to be successfully commercialized

  - DRUGS (small molecules + biologics)
  - MEDICAL DEVICES
  - DIAGNOSTICS
  - COMBINATION PRODUCTS

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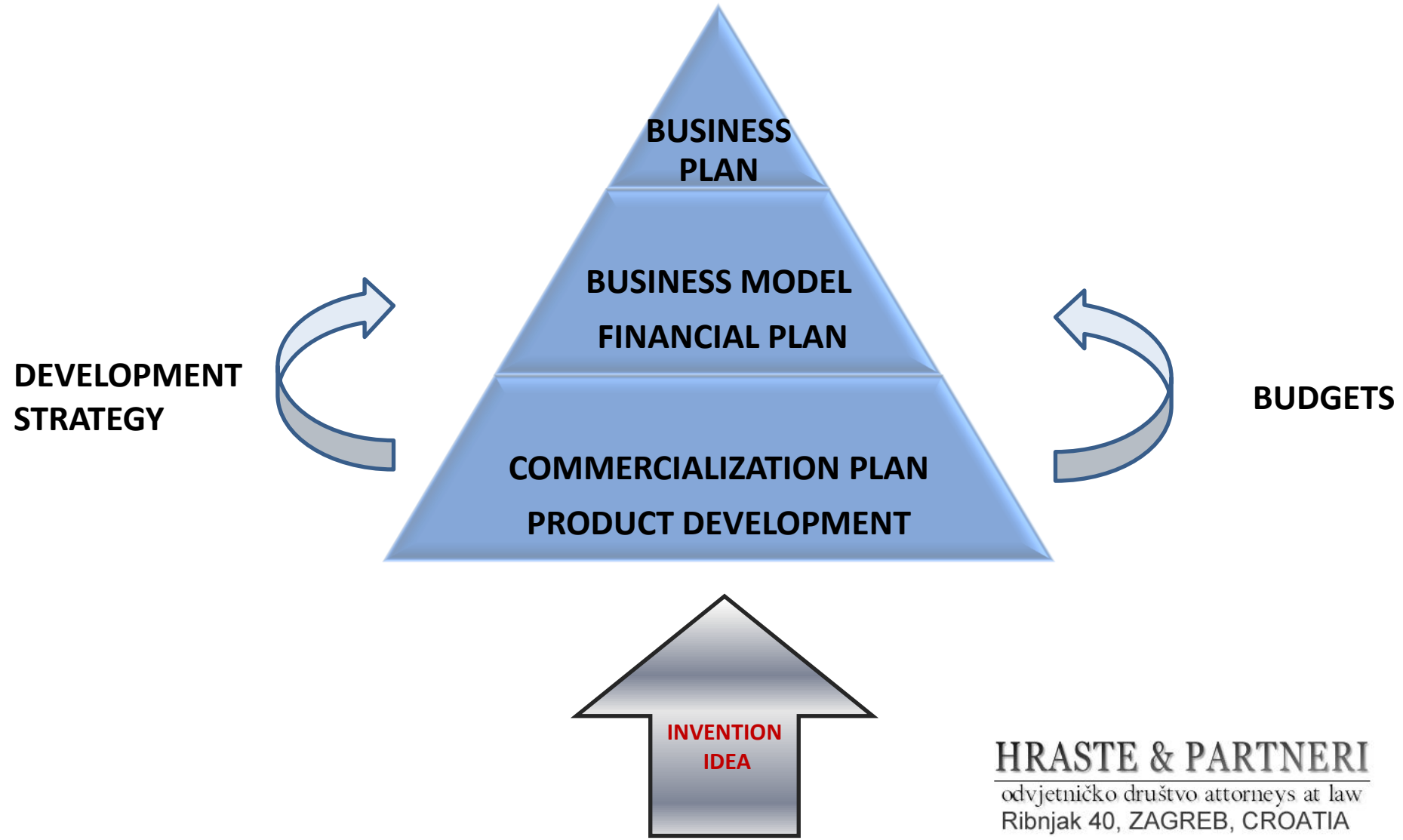
Commercialization of biomedical research



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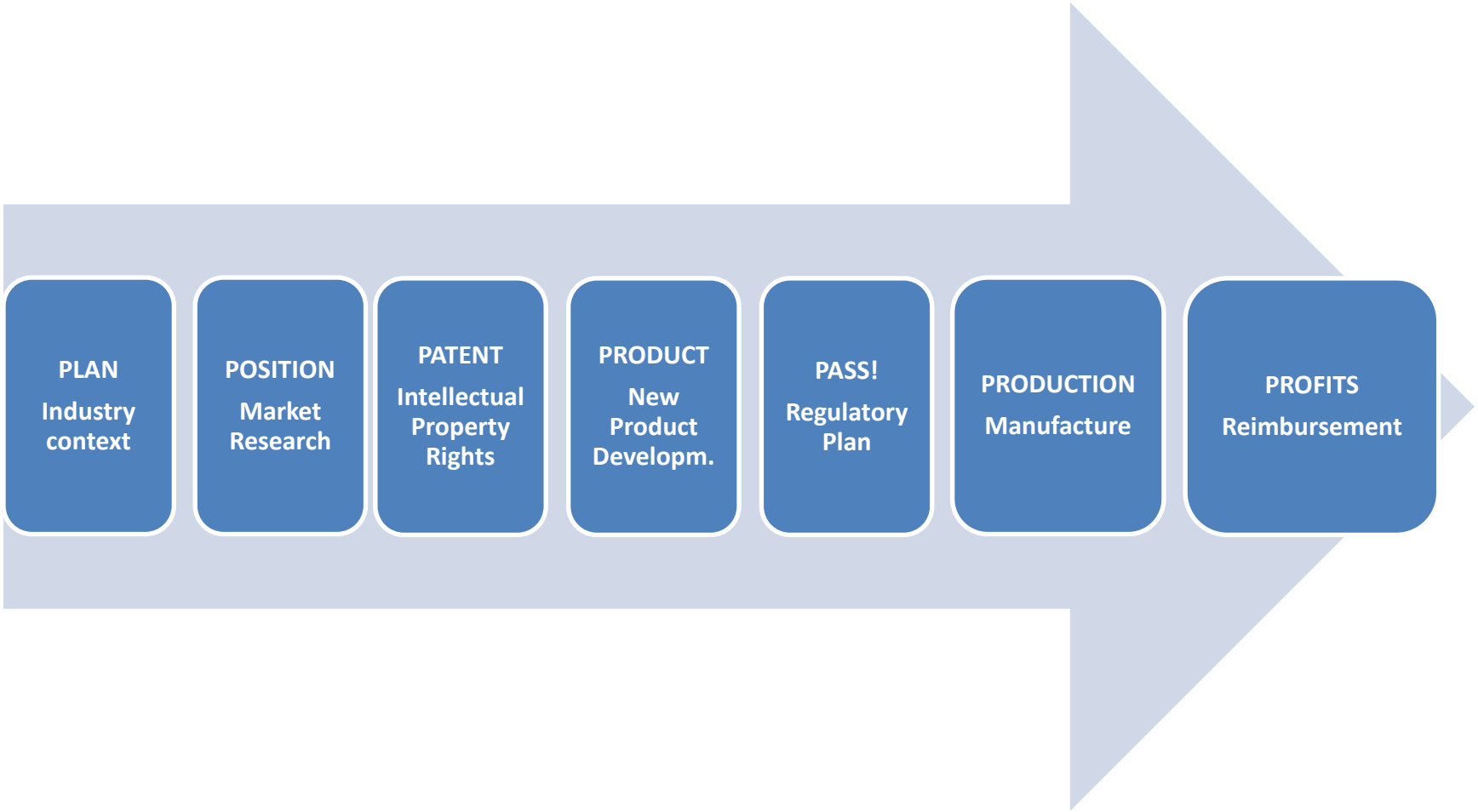
Commercialization plan



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Commercialization plan

- PLAN
  - Technology positioning and strategy
- MARKET
  - Market need
  - Market size and segments
  - Product characteristics
- PATENT
  - IP Management and licensing strategy

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Commercialization plan

- PRODUCT
  - Testing and development
- PASS!
  - Regulatory strategy
- PRODUCTION
  - Manufacturing

- PROFITS
  - Marketing , sales planning
  - Payment, distribution

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Legal requirements for patentning an invention

- Novelty
- Involve inventive step
- Industrial applicability

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Patent databases

- http://www.google.com/?tbm=pts
- http://worldwide.espacenet.com/?locale=en_EP
- http://patentscope.wipo.int/search/en/search.jsf
- Croatian Intellectual Property Institute
- http://www.dziv.hr/

Public disclosure

- Any disclosure prior filing a patent will result in the invention no longer being patentable
- Examples:
  - Informal discussion outside your organisation
  - Postings on the web
  - Talks at the meetings
  - Chat with collegues
  - Abstracts
  - Posters
  - Unprotected E-mail

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What is patentable?

- ***European Patent Convention***
- *Article 52*

Patentable inventions

(1) European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.

- (2) The following in particular shall not be regarded as inventions within the meaning of paragraph 1:
- (a) discoveries, scientific theories and mathematical methods;
- (b) aesthetic creations;
- (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
- (d) presentations of information.

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What is patentable?

- (3) The provisions of paragraph 2 shall exclude patentability of the subject-matter or activities referred to in that provision only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such.
- (4) Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

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What is patentable in biotechnology field?

- Non-living entities
  - DNA, recombinant DNA genes, promoters, plasmids, vectors, polypeptides, antibodies

- Living enities
  - GMOs and plant and animal cultures

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Can genes, ESTs or SNPs be patented?

- EPO and USPTO differ in the stance on patentability of
  - genes
  - Open rading frames that are not expressed
  - EST (expressed sequence tags)
  - SNP (single nucleotide polymorphism)

  - USPTO - identification of a gene's sequence alone is not patentable, but that a gene isolated from its natural state may be patentable if the applicants can demonstrate "specific, substantial and credible utility" for the discovery

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Who should be listed as an inventor on a patent?

- Only those who have made independent, conceptual contributions to an invention
  - Patent could be invalidated in case others are listed
  - In order to avoid any conflict with regards to personal recognition, royalty payments, license fees, etc.

Filing procedure

- Filing a complete or provisional application
  - Provisional patent application is usually filed when the invention is still under development and is likely to be changed over the next year
  - In Croatia it is not possible to file a provisional application
  - USPTO, UKPO – it is possible

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Filing procedure

- Application headings:
  - Field of invention
  - Background of invention
  - Objectives of invetion
  - Summary of the invention
  - Detailed description of the invention and/or description of the drawings
  - Claims

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Filing procedure

- The priority date
  - The date on which the patent application is field
  - From this date invention is protected
  - The applicatn is given world-wide pending rights for one year from the priority date

  - The 12 months from the priority date can be used for further development of the idea, to assess the commercial potential

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Filing procedure

- The priority date
  - If after 12 months it is clear that the invention can not be exploited – the patent can be abandoned or withdrawn
  - At the end of 12 month period, a complete patent specification has to be filed

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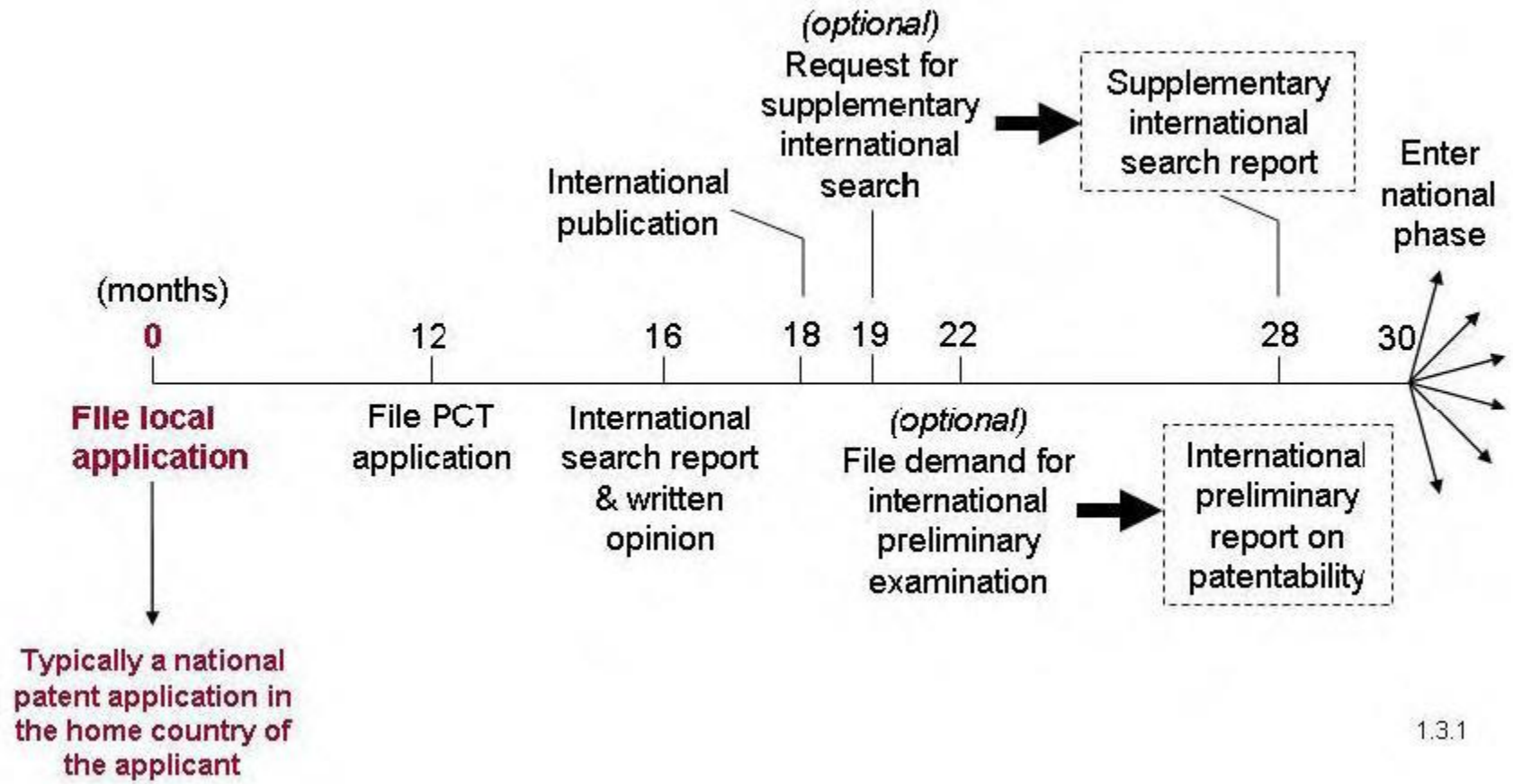
PCT (Patent Cooperation Treaty)

- One application – 100 countries (PCT contracting states)
  - PCT application buys you 18 months extra time to evaluate the marketability of the invention before incurring huge patenting costs involved in the “national phase”

Filing procedure



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National phase

- To file complete patents in each of the countries in which protection is required
- It can be extremely costy
- Each patent office will conduct a full examiantion of the patent to determine novelty, inventive step and industrial applicability

Patent term and patent term extensions

- Basic patent - 20 years

- For a medical product in some designations SPC – maximum 5 years
- Paediatric extension – 6 months

- Progressive annuity payments have to be paid to maintain the patent validity

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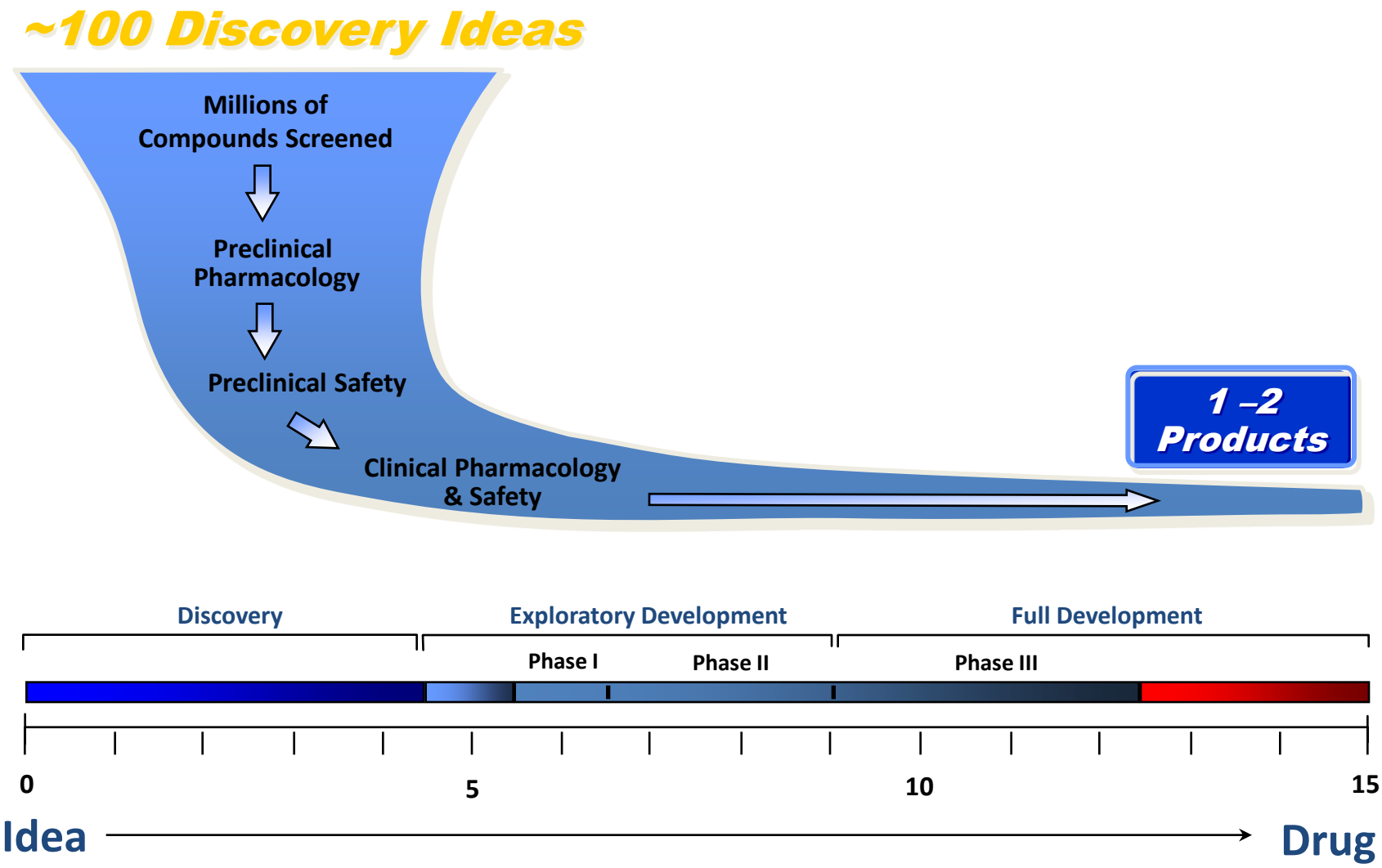
Drug Discovery Process



Drug Discovery Process

Complex disease targets

Cost

Adverse reactions

Poor absorption

Low levels in body

Not effective enough

Intellectual Property

Not sufficiently selective

Side effects

Unsafe

Unstable

Competition

Impractical to make

Confidence in Rationale

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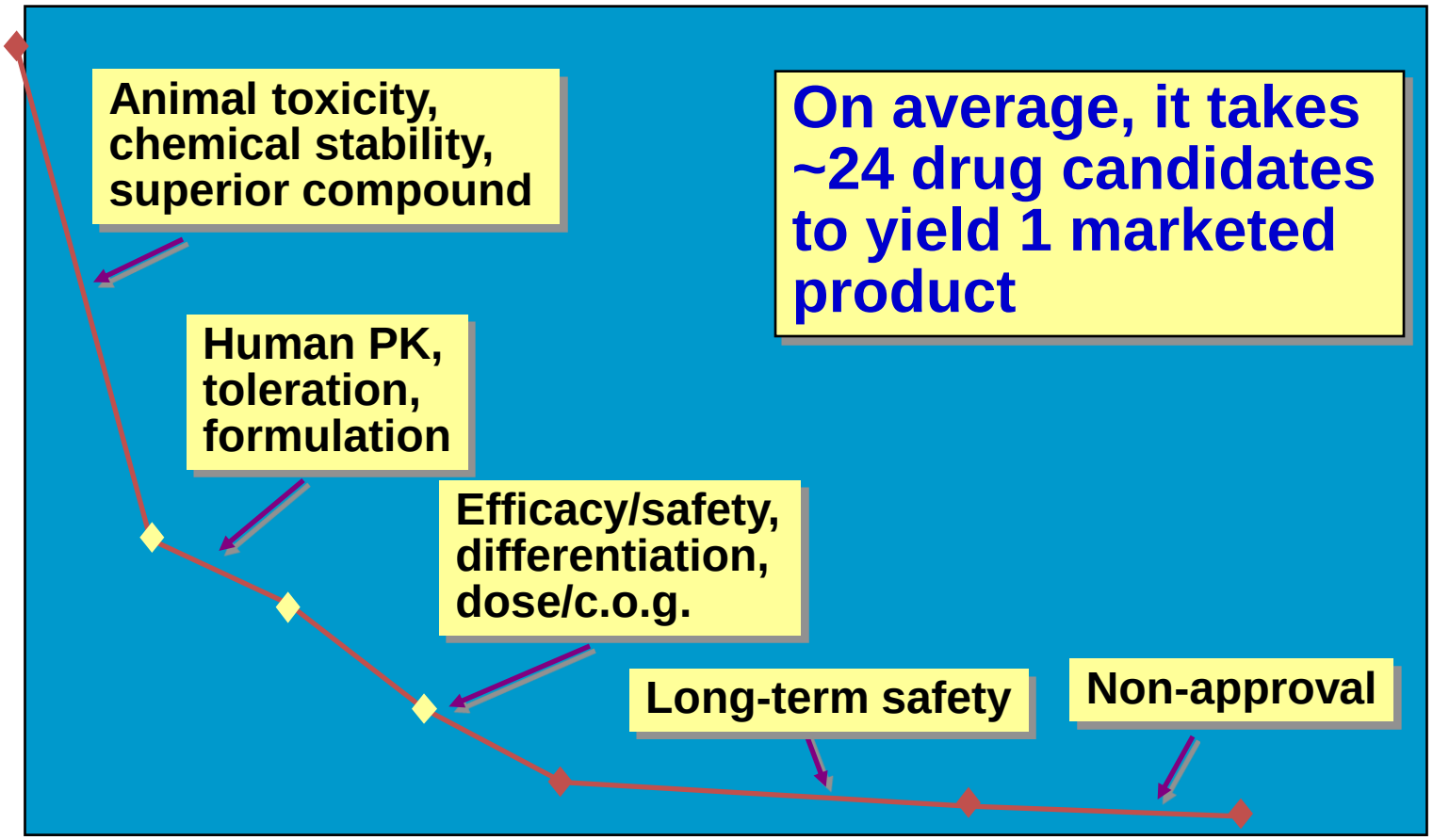
Drug Discovery Process



Successfull stories

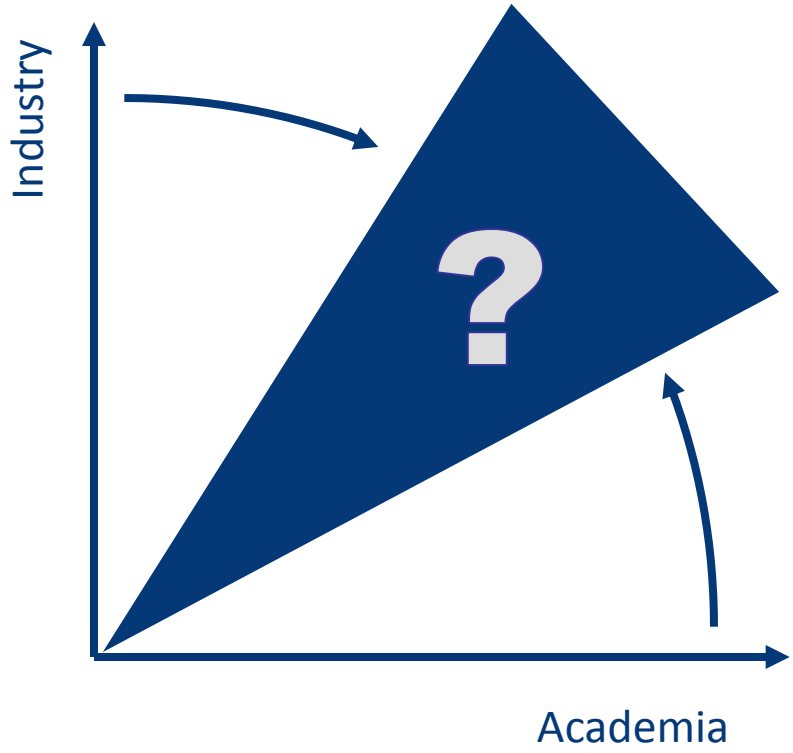
- http://depts.washington.edu/uwc4c/news-events/category/case-studies/life-sciences/
- Innovation
- Molecule NTx is a specific protein fragment of bone collagen produced upon bone resorption and released into the bloodstream
- Commercial test development
  - Used for osteoporosis diagnosis
- Licence or spinoff ?
  - Ostex International
    - Osteomark®NTx commercial test
    - FDA approved
    - Gradually expanded (1989-1995) from 4-60 employees

Successfull stories

- Ostex went public in 1995 with $35- million IPO
- Originally inventors thought than it will replace or augment the standard clinical methods
- Health care industry was not ready to abandon X-rays and bone scans
- Ostex was generating $5-million per year in sales but this was not enough to investors
- Company was sold to Inverness Medical Innovations
- Pharmaceutical companies have developed drugs to treat bone loss, products that have now large markets
- The precision and reliability of the Osteomark NTx made it an ideal assay to analyze the effectiveness of their drugs during their development
- Pharmaceutical companies are now the biggest buyers of Osteomark NTx

Science-industry collaboration

How to overcome barriers?



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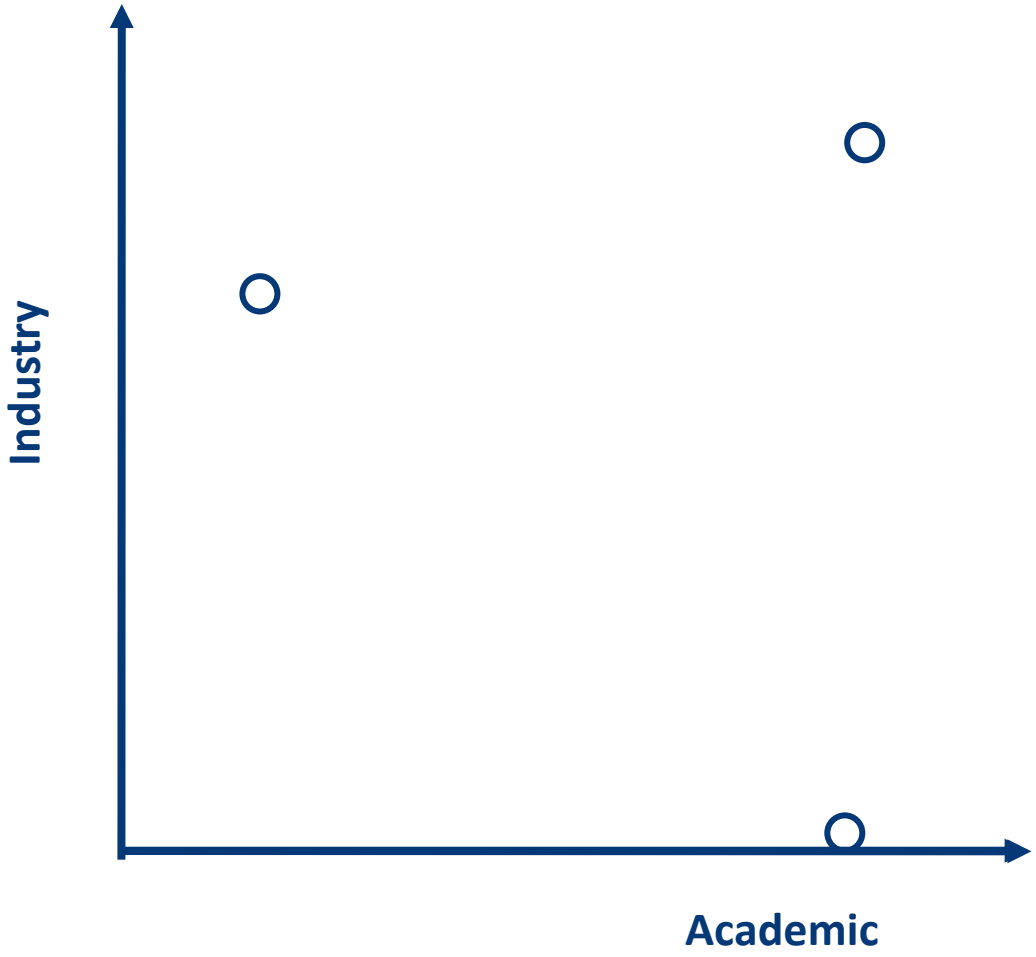
Where are you?



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THANK YOU FOR YOUR ATTENTION!

HRASTE & PARTNERI j.t.d. ODVJETNIČKO DRUŠTVO

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ZAVODU ZA INTELEKTUALNO VLASNIŠTVO

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