



A Systematic Approach to Developing New Biotechnology Capacities and Capabilities

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Biotechnology

Biotechnology is any technologic application that uses biological systems, living organisms, or derivatives thereof to make or modify products or processes for specific use.

- UN Convention on Biological Diversity

The 21st Century: The Century of Biology

- 20th Century was Century of Physics
- Great discovery science and conversion to products (e.g. silicon transistor)
- Future of living species demands better understanding of biological systems and real products to improve the well being of people, animals, and plants

Some Biotechnology Arenas

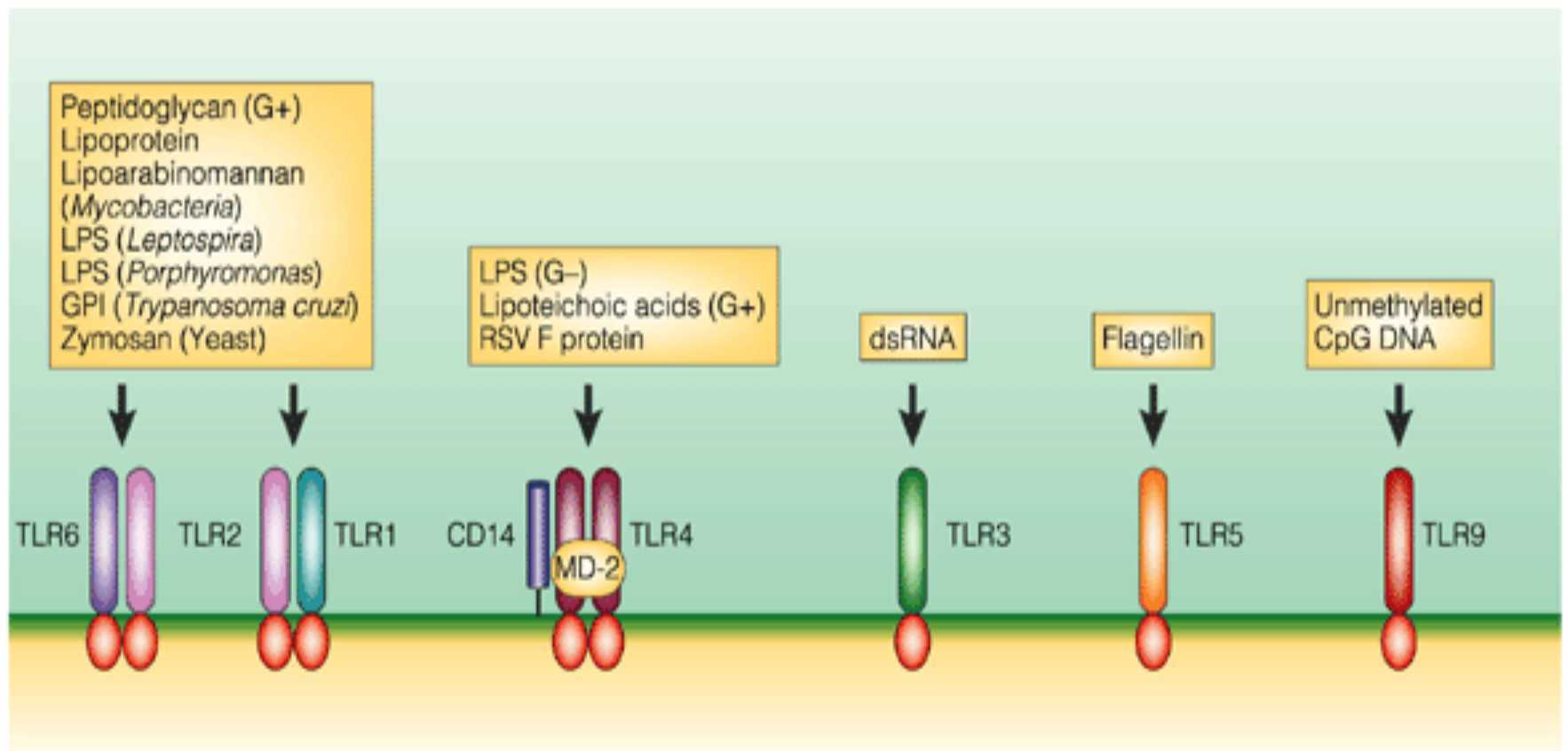
- Chemical Engineering
- Bioprocesses Engineering
- Bioinformatics
- Biorobotics

Establishing an Enterprise is Critical to Progress

- Discovery Science
 - Advanced Development
 - Manufacturing
 - Real World Usage
- 

An Example of Discovery Science

- Toll Like Receptors (TLRs)
- Identified in 1985 in *Drosophila*
- Protein in cell membrane
- Pattern recognition receptor 13 identified in humans
- Alert immune system and lead to immune activation
- TLR-5 is activated by flagellin proteins, inhibits cell self destruction, activates G-CSF, IL-6



Nature Reviews | Immunology

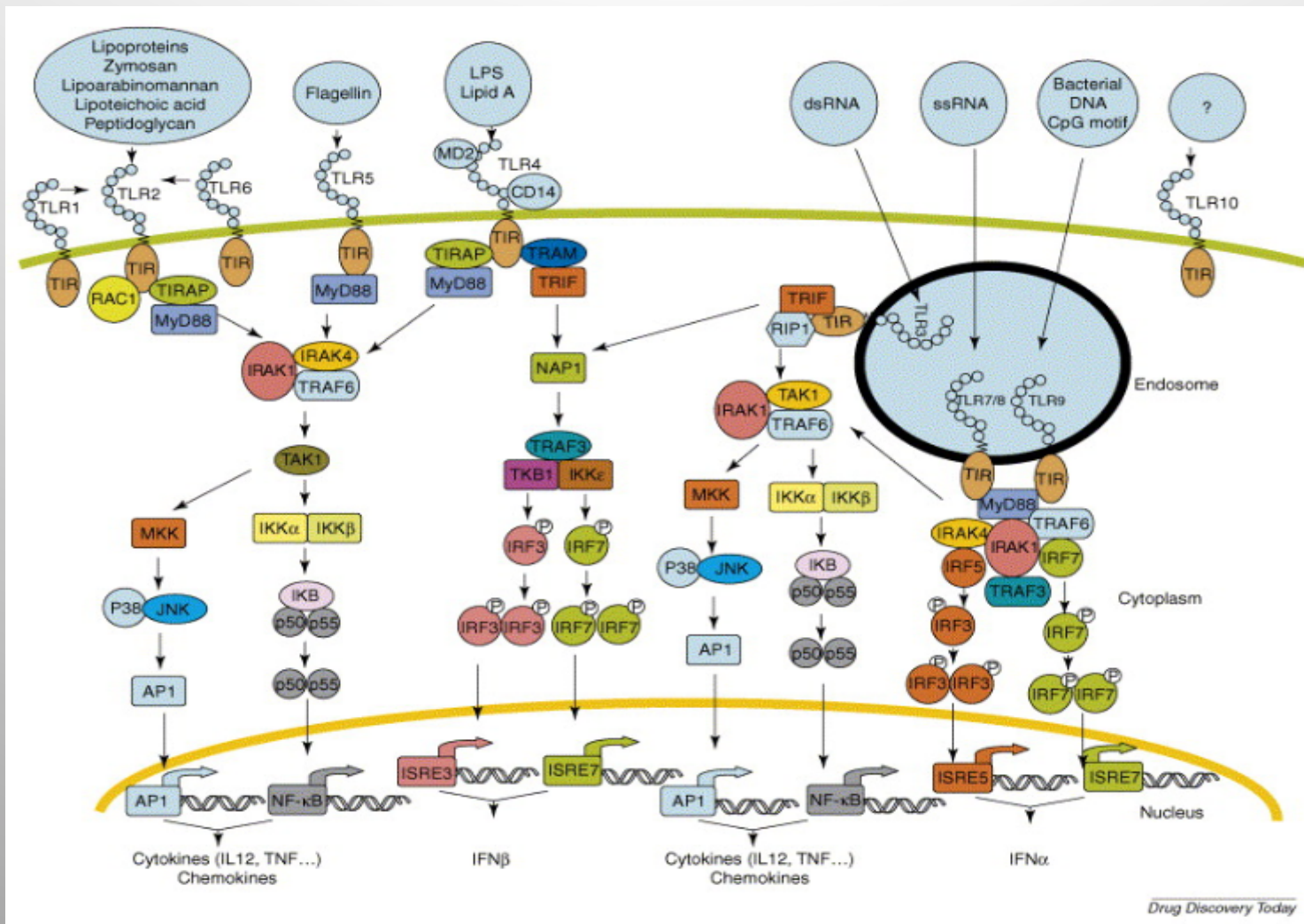
FIGURE 3 | Ligand specificities of TLRs.

FROM THE FOLLOWING ARTICLE:
[Toll-like receptors and innate immunity](#)

Ruslan Medzhitov

Nature Reviews Immunology 1, 135-145 (November 2001)

doi:10.1038/35100529



Drug Discovery Today

Volume 12, Issues 1-2, January 2007, Pages 80-87



Current and future drugs targeting one class of innate immunity receptors: the Toll-like receptors

Francois Romagne

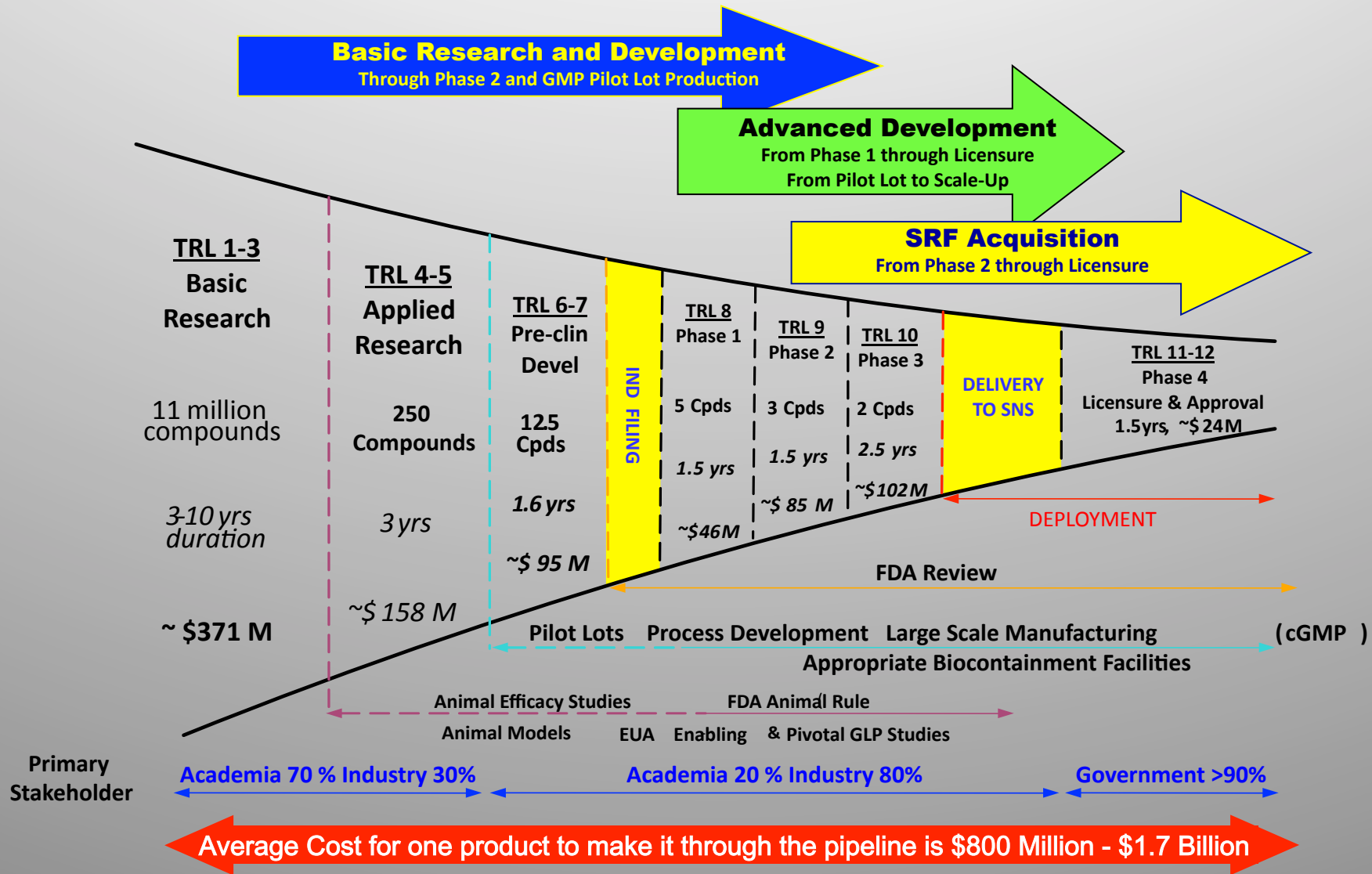
Innate Pharma, 121 Ancien Chemin de Cassis, 13009 Marseille, France

<http://dx.doi.org/10.1016/j.drudis.2006.11.007>

An Example of Advanced Development

- Theory: Stimulating the TLR-5 receptor will protect tissue exposed to ionizing radiation
- Advanced development requires animal and human testing for safety and efficacy
- Very costly to develop and has less market as start up activity and requires multi-disciplinary effort
- Mouse, NHP, and human trials funded under enterprise approach

The Challenges of Countermeasure Development



Establish a Strategic Enterprise

- Establish vision/mission and oversight or governance body
- Establish strategic goals (identify needs/uses and prioritize)
- Identify institutions and capabilities and gaps
- Identify funding streams

Establish Defined Process for Development

- Analyze discovery science for promising efforts (“Techwatch”)
- Establish advanced development center to assist in clinical studies and production
- Meet quality standards for safety and efficacy of products and process
- Strengthen educational institutions and global linkages

Primary Skills Needed Exceed Technical Knowledge

- Technical
- Programmatic
- Managerial
- Fiscal
- Political

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Questions?

