Prospective Workshop

Essec Santé – Centrale Santé

"Will the Pharma « bubble » collapse within 3 years?": Yes!

Key Learnings and proposals

The three presentations topics (click on the links to download the presentations):

1. Why payers' reimbursement strategies should have a significant impact on the Pharma research paradigm*? Caroline Conti, Senior Consultant GfK Market Access.* Poster
2. Analysis of pharmaceutical research and development. What slows R&D productivity? *Goulven Theze, Business Development, Health Economics Outcomes Research, Statitec.*
3. Why are we in trouble, the bubble deciphered, new vision, new paradigm, novel strategies, the serial killer of disruptive innovations identified, key learnings and recommendations. *Manuel Gea, Co-founder & CEO Bio-Modeling Systems.*

The answers to three critical questions that are detailed below in this document and deeply explained in the three presentations:

1. What is the Pharma-biotech bubble? *The genetic-based targeted (individualized) cancer therapies.*
2. When will the bubble collapse? *The reimbursement of these therapies will be requested within 3 years.* They will not be reimbursed for two main reasons. *They are too expensive in any case, and they do not work on the long term!*
3. What is the disruptive innovations serial killer? *The experts' consensus evaluation process of the R&D programs.*

BMSystems' Presentation outputs:

Summary of the BMSystems' Presentation

Key learnings in life sciences issues

- The mechanisms of life are complex, non-linear and integrative. They are "built" to survive.
- In "living complex" systems, the functions of biological components and mechanisms are event and context-dependent.
- Classical "Cartesian" modeling concepts & approaches, valid for the majority of man-made artifacts, imply the concept of a "blue-print". But this concept is at the opposite of biological reality
- … While "Cartesian" Bioinformatics and Mathematical tools have proven to be efficient to collect, structure, analyze, simulate specific functions to test or to generate innovative hypotheses, yet…
- …The "garbage in, garbage out" reality, tells us that the information produced and published (even in leading scientific journals) is necessarily ALWAYS incomplete, biased and erroneous to unknown extents.

What must be clarified to change the R&D paradigm?

- In life sciences, with less than 10% success rate, a dominant recurrent thinking that fails may be "false"!, even if supported by Key opinion leaders.
- The Academic World is not "the only" source of innovations.
- "Discovery" means finding "unknown" facts.
- Simulating a system supposes to have understood and described it before beginning with.
- In life sciences, Big Data may lead to Big Garbage if the data produced are not correctly contextualized.
- "New therapies" do not necessarily mean new drugs.
- Combinations of existing drugs are patentable!
- The cost of drug development is not 1 billion € per drug for a SME. It is around 250 M €, but in case of failure the SME is "dead".
- Scientific Proof of concept on humans does not mean clinical trials.

- The oncology Individualized therapy bubble.
- Nevertheless, it MUST be remembered that Models are Aids to thought, NOT a replacement for it!!

Proposals to develop Integrative Biology teams

- Develop new training programs for the future integrators through smart selection processes and open minded educational organizations.
- Develop multidisciplinary training programs for both IT integrators and biology Integrators to build complete Integrative biology teams.
- Create for these "high level generalists" "successful" job evolutions adapted to their specificities and profiles.
- Introduce "general semantic" and other "soft" knowledge in life sciences and technologies educational programs to train people think "out of the box".
- Re-introduce physiology in the educational programs.
- Support and protect people who think different.
- Systems biology must be considered as a biology driver research process supported by IT tools to help them work.
- Could we say, being provocative, that we need more "Dr. House" type of MDs and biologists in our medical research teams!

Key learnings and proposals to really support disruptive innovations champions

- The experts' consensus evaluation process, well adapted for incremental innovation evaluation, is clearly the number one serial killer of disruptive innovation.
- Disagreement amongst experts should be considered a necessary, but not sufficient, condition to detect disruptive innovations.
- The great disruptive discoveries come from challengers such as Pasteur who discovered that most infectious diseases were caused by germs against the medical establishment since Felix Pouchet in 1859 had published a prevailing work in favor of spontaneous generation theory.
- Similarly the Australian scientists Barry Marshall and Robin Warren were obliged in 1984 to infect themselves with Helicobacter pylori to prove that it was the gastric ulcers cause.
- Three types of Innovations are complementary: technology, organizational and usage innovations must be equally supported and evaluated.
- A specific evaluation track could be defined: evaluation of the innovation by experts of the domains where the technology comes from, and by open minded potential users of the innovation applications.
- 25% of institutions/companies R&D budgets should be dedicated to this specific track.
- Research "supposed of no interest" for industry or VCs should be supported and funded to prepare the future and regenerate diversity of concepts and ideas.
- Develop multidisciplinary team spirit and training built on already existing prototypes that can gain support (example: Alliance of Essec Santé, Centrale-Santé and FSM).

The Pharma bubble: The oncology Individualized therapy bubble

- The Individualized therapy mirage vs. multi-therapies novel concept
- A tumor is rarely composed of one type of tumor cell.
- Brest cancer example: multiple types of cancer cells within the same tumor.

- Targeted treatment does nothing more than selecting resistant cancer cells: The cancer first diminishes & then starts again and cannot be stopped.
- BMSystems through his 3 programs, identified the narrow limits of mono-targeted therapies and proposes a new approach to oncology research, based on a therapeutic strategy that does not only target the tumor inside but uses the possibilities of surrounding tissue to control metastatic processes while starving cancer cells.

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