Summary

Knowledge Transfer Pathways from Research to Patient Treatment

Science - Communication - Innovation Management - Clinical Investigation

International Workshop on September 28, 2018 at House of Scientists in Lviv

Develop – It is the nature of research Scientists to develop new methods, markers, tests, and instruments.

Aware – Scientists realize the scientific value of their research and apply for protection of their research output.

Accept – Scientists publish their results to motivate other scientists, advance their research, and gain acceptance of novelty by the scientific community

Investigate – Bringing into medical practice the newly developed diagnostic or treatment modalities starts with market research to investigate the market value and benefit for medical practice.

Demonstrate – Initiate clinical research to demonstrate that the invented methods, markers, tests, or instruments can perform the predicted non-harmful, well-defined medical applications.

Agree – The medical community accepts, and the interested companies realize the market opportunities.

Benefit – Investigate the cost versus benefit of the new application in medical practice.

Develop – **It is the nature of research Scientists to develop new methods, markers, tests, and instruments.**

Research Plan

Hypothesis

Goals

Methods

Expected Outcomes

Presentations and Protection

Implementation of Research Plan

Basic Research – **drug development,**

biochemical reactions could lead potential biomarkers

genome sequencing for diseases prevention and treatment

molecular and cellular pathways to explore development of diseases (metabolic,

inflammatory, degenerative)

Implementation of Research Plan

Translational Research to investigate disease development and progress

Markers (adipokine, cytokine)

Cellular biochemical mechanism (apoptosis)

Change in regulations and interactions (mitochondrial disfunction)

Genetic and cellular regulation interaction (epigenetic)

RECOOP HST ASSOCIATION

Research Mediums

Means (what, why and how?)

Cells, Organs, Animals, Human (IACUC, EC)

Method: Instruments and Agents

Avenues (Material Transfer and None Disclosure Agrement)

Outcome Documentation (log books, electronic recording)

Statistical Power

Aware – **Scientists realize the scientific value of their research and apply for protection of their research output.**

Protect and Publish

Technology transfer is the process of turning scientific research results into business opportunities.

Formally transforming research results into practical applications with commercial potential,

Seeking intellectual property protection for these innovations

Transferring them to industry via license agreements or sometimes spin-off companies

Create a balance between the broad public interest and the interests of industry, the public research organization and the researchers

Various forms of IP protection (land mind or tree trunks)

***Aware* – Scientists realize the scientific value of their research and apply for protection of their research output.**

Art and skills for negotiation – an essential component to bring the licensing transaction to completion.

Deal making is not a zero-sum game.

Strategically structure your deal to gain the maximum value

Reach agreements which both sides of the table are content

Building a long-lasting relationship with your licensee – industrial grants

Accept – **Scientists publish their results to motivate other scientists, advance their research, and gain acceptance of novelty by the scientific community**

The young scientists' research efforts and results would be publishable.

The novelty and the implications of the findings need to be analyzed.

Reflection of the good study design and creating the documentation

The hypothesis and the aims defined from the begging of the study lead to good publications

Accept – **Scientists publish their results to motivate other scientists, advance their research, and gain acceptance of novelty by the scientific community**

The shapes of the future paper having the IMRAD (Introduction, Material and Methods, Results, and Discussion).

Easy to transfer to the conference presentations and to the final publications.

Midterm on long run research strategy based on well-defined the hypothesis-driven approach

Building of each scientific identity.

Accept – **Scientists publish their results to motivate other scientists, advance their research, and gain acceptance of novelty by the scientific community**

Study literature
MEDLINE is a bibliographic database of life sciences and biomedical information. It includes bibliographic information for articles from academic journals covering medicine, nursing, pharmacy, dentistry, veterinary medicine, and health care.

ResearchGate
Google Scholar

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Study articles and investigate

a., Similarities in the manuscripts to your work

b., Differences

c., Goals and methods you could use to improve your study.

Accept – **Scientists publish their results to motivate other scientists, advance their research, and gain acceptance of novelty by the scientific community**

Major danger to be encountered in own research would be producing bad science

Plagiarism

Research Misconduct

Easy way – open access (pay and enjoy)

Accept – **Scientists publish their results to motivate other scientists, advance their research, and gain acceptance of novelty by the scientific community**

Mistakes in Statistical Methods

Statistical significance (would be successful in 1/20 comparisons ($p<0.05$)

Several groups, several measured parameters in the groups in different time scale you should run an analysis of variance (ANOVA). It is a collection of statistical models and their associated estimation procedures (such as the "variation" among and between groups) used to analyze the differences among group means in a sample.

Investigate **– Bringing into medical practice the newly developed diagnostic or treatment modalities starts with market research to investigate the market value and benefit for medical practice**
How to understand the value proposition of your inventions –

Novelty

Conduct market research and identify industry – Medical Practice

How best to position your technology by showcasing competitive advantages - New diagnostics or treatments

Resources and tools for market analysis and identifying prospective licensees.

Investigate **– Bringing into medical practice the newly developed diagnostic or treatment modalities starts with market research to investigate the market value and benefit for medical practice**
How to understand the value proposition of your inventions –

How to develop marketing strategy

Write effective technology summaries

Market the technology to the appropriate industry contact to assess licensing interest.

Demonstrate **– Initiate clinical research to demonstrate that the invented methods, markers, tests, or instruments can perform the predicted non-harmful, well-defined medical applications.**

Clinical research is performed to learn how to improve medical treatments, health care and public health.

It allows experiments conducted in the laboratory into the realm of clinical medicine.

A short overview of the proper conduct of clinical research:

- **Interactions and relationships with basic research and translational research**
- **Activities during implementation**
- **Regulations and guidelines (Standard Operating Procedure - SOP) regulated national and international agencies**

***Demonstrate* – Initiate clinical research to demonstrate that the invented methods, markers, tests, or instruments can perform the predicted non-harmful, well-defined medical applications.**

The principle known as Good Clinical Practice or GCP - detailed in the International Council for Harmonization [ICH] Harmonized Tripartite Guideline (ICH-GCP)

It is the gold standard in the ethical conduct of clinical research.

The phases of clinical trials, a type of clinical research (industry or agency or self sponsored),

Quality management (QM) is including the Food and Drug Administration (FDA) recommendation of risk-based monitoring (RBM).
RBM was adopted by the European Medicines Agency (EMA) in November 2016 and is now an addendum of ICH-GCP.

Agree **– The medical community accepts, and the interested companies realize the market opportunities.**

Specificity and Selectivity comparing to the traditional and existing diagnostics and treatments

Easy to adopt to the daily practice

Accessible (price)

Cost benefit for the patient and the health care system

Benefit **– Investigate the cost versus benefit of the new application in medical practice.**

The contingent valuation method, which clearly demonstrates the moral dilemma of the monetary value of health (or even human life) through the measurement of willingness to pay.

Cost minimization, when we can see how to achieve efficiency through early stage diagnosis. By comparing two methods of oncology screening, I present the capability of this decision-making method.

Benefit **– Investigate the cost versus benefit of the new application in medical practice.**

Cost-effectiveness analysis demonstrate the gain can either be an intermediate parameter (stent) or new healthcare technologies (MRI).

Cost-utility analysis has major elements:
Quality-adjusted life-year methods (QALY, DALY).
These methods are suitable for ranking all existing modalities (treatment with dugs, or using technologies (balloon catheter- stent)

Cost-benefit analysis in the process of social decision-making for the benefit for the patient (resource allocation).

Conclusion

The ongoing process of knowledge integration is removing territorial borders and fostering research collaborations to expedite laboratory research transformation into practice via the steps of Knowledge Tranfer: Develop: (1) Aware, (2) Protect, (3) Accept, (4) Investigate, (5) Demonstrate, (6) Agree, and (7) Benefit.

The Knowledge Transfer Chain ™: *Develop – Aware – Protect – Accept – Investigate – Demonstrate – Agree – Benefit (DAPAIDEB)* helps the advancements of biochemistry and molecular biology gained through various laboratory techniques to develop new ways to treat patients and are key for Innovative Medicine.