Pharma and Evidence generation – What is the future?

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Medical Affairs, Janssen Nordic

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Johnson & Johnson family of companies
– Broadly based in Human Health

Johnson & Johnson

- Advanced surgical products through Ethicon, DePuy Synthes and Biosense Webster
- Innovations for surgical purposes
- Advancing the future of surgery

Janssen
PHARMACEUTICAL COMPANIES OF Johnson & Johnson

- Portfolio includes Neuroscience, Oncology, Vaccines, Immunology, Infectious Disease, Metabolism and Pulmonary Arterial Hypertension

Johnson & Johnson
CONSUMER PRODUCTS COMPANY
DIVISION OF JOHNSON & JOHNSON CONSUMER COMPANIES, INC.

- Natusan Baby Care
- Imodium Digestive Health
- Nicorette Smoking Cessation
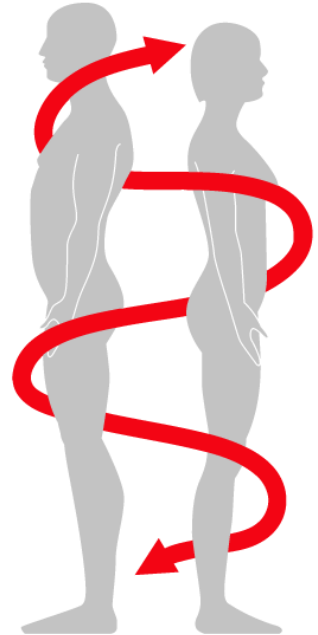
A long process with limited data points

RESEARCH   DRUG DISCOVERY   PRE CLINICAL   CLINICAL TRIALS I-IV   LAUNCH   PATIENT

Evolution of Evidentiary Needs
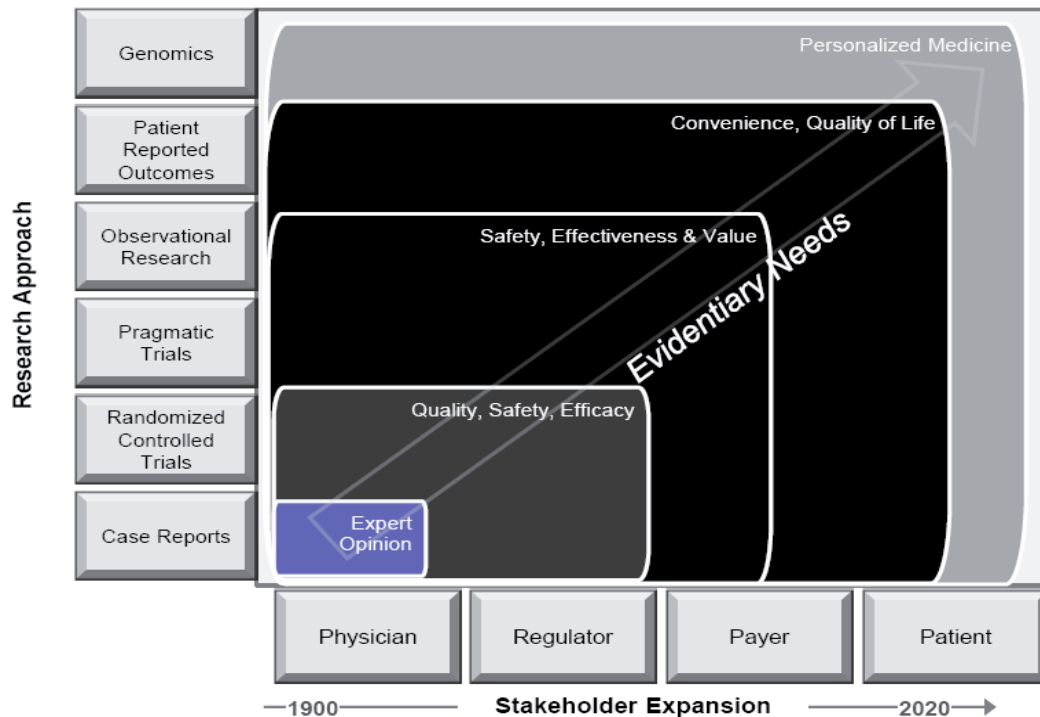
Post-Approval Environment:
EMA enhances the generation of RWE

Safety Safety Safety Safety

RW E
H E O R

20/15   50 FT / 152 M
20/20

Effectiveness Benefit-Risk Effectiveness Benefit-Risk

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A new paradigm in medical research

New technology and methodologies now enable top-ranking research from real world situations.

Real world evidence research is often based on:

- Analyzing multiple sources of data from multiple stakeholders, health systems, disease registries, medical records, trials
- Observational study design
- Larger, more heterogeneous patient groups

Real world evidence changes the way we measure outcomes.

- **Aims to study medical interventions in real world situations**
- **Broader range of parameters from multible sources of data**
- **Informs the development of new therapeutic solutions**

Janssen's global real world evidence network

Janssen is partnering with top institutions worldwide to accelerate this new line of research.

Our network aims to:
- Apply scientific best practices
- Advance methodologies
- Generate evidence on
  - disease pathways
  - healthcare delivery
  - effects of medical interventions
- Support medical decisions and identify new medical breakthroughs

Canada

Sweden

Hungary

USA

Korea

Taiwan

Data Harmonization/Standardization

Observational Health Data Sciences and Informatics (OHDSI) - program

- Multistakeholder collaboration to create open-source solutions for large scale analytics

- A rapidly growing international network for open science and data analytics in healthcare

- Focus:
  - Data standardization (Common Data Model)
  - Collaborative research
  - Large-scale analytics
  - Sharing of tools and methodologies

- OHDSI –1 billion patients

Unique opportunity for Nordic life science

Thanks to the Nordic data infrastructure, this region can become a hot-spot for advanced medical research by enabling uniquely comprehensive and long term studies.

Janssen is partnering with Karolinska Institute in a major collaborative research initiative[1] that focuses on:

- Treatment resistant depression
- Prostate cancer
- Psoriasis
- B-Cell malignancies
- Methodology development

Janssen's real world evidence network also facilitates collaboration in other disease areas, across Nordic institutions.

10%
Of all global real world evidence research originates from Nordic.
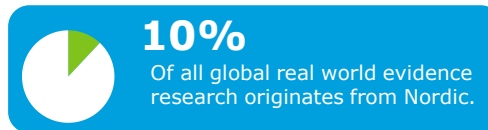
Finland is in the forefront of health data digitalization

- **Public healthcare system today boasts electronic healthcare record (EHR) penetration at 98%**
  - paperless referrals at 95%
  - EHR information exchange capability of 90%

- **National digital patient data repository (Kanta)**
  - covers both the public and private healthcare sectors
  - Finland is among first countries in the world

- **E-prescription history**
  - All Finnish citizens now have on-line access to repository services

- **Upload personal health information**
  - choose to grant access to your own data to health care professionals

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Comprehensive digital Health, Social and Welfare Registries in Finland

NAME OF REGISTER	DATA INCLUDED IN REGISTER	KEEPER	ESTABLISHED IN COMPUTER FORMAT
Hospital Discharge Register (HILMO)	Homes and institutions for the mentally disabled, including information on treatment	THL	1967
Finnish Registry for Kidney Diseases	Diseases, type of treatment, and laboratory tests	ETK	1964
Cancer Register	Cancer patient information from hospitals, pathology, laboratory measurements etc.	THL	1953
Finnish Register of Visual Impairment	Patient's visual ability	THL	1983
National Infectious Diseases Register	Detailed information on cases in infectious diseases	THL	1989
Register of Congenital Malformations	Infants and foetuses	THL	1963
Drug Reimbursement Registers	Disease that is being treated and medication used	KELA	1967
Medical Birth Register	Information on all births in Finland, from gestation week 22+0 or birthweight 500g	THL	1987
Cause-of-Death Register	Intermediate case of death and contributing causes of death	STAT	1969
Register on Occupational Disease	Diagnosis of occupational disease	FIOH	1964
Drug Surveillance Register		FIMEA	1982
National Sickness Insurance	Social benefit information	KELA	1967
Register on Pensions	Work pension information, age of individual, type of pension	ETK	1962
Finnish Employment Register	Work in private sector, work as entrepreneur and work without pay	ETK	
Central Population Register	Relations (stillbirths are not registered)	VRK	1973
Register on Social Assistance		THL	1985
Child Welfare Register	Individual-level information on children taken into custody	THL	1991

THL = National Institute of Health and Welfare
ETK = The Finnish Kidney and Liver Association
KELA = Social Insurance Institution

STAT = Statistics Finland
FIOH = Finnish Institute of Occupational Health
FIMEA = National Agency for Medicine

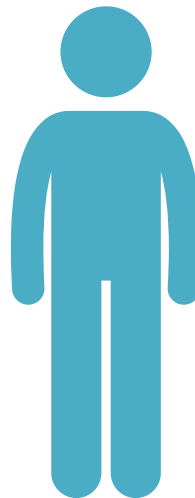ETK = Finnish Centre for Pensions
VRK = Central Population Register

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Engaged People: Finns Trust Researchers and Want to Participate

95 % OF SAMPLE DONATORS HAVE GIVEN CONSENT OF THEIR SAMPLES

85 % OF 340 000 WOMEN PARTICIPATED IN SCREENING OF BREASTCANCER

> 85 000 PEOPLE PARTICIPATED IN VACCINATION RESEARCH (2010)

> 30 000 PEOPLE VOLUNTEERED FOR 284 DIFFERENT MEDICAL STUDIES (2013)
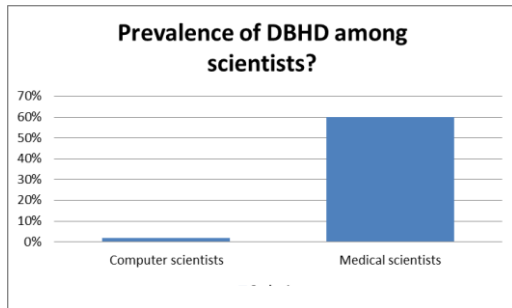
POPULATION 5,5 MILLION

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Pros and Cons

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OF BREASTCANCER

> 30 0
PEOPL
FOR
M

POP'

Engaged people

Comprehensive

Linkage

National

Family

Fragile

Infrequently updated

Prevalence of DBHD among scientists?

70%
60%
50%
40%
30%
20%
10%
0%

Computer scientists   Medical scientists

Data accessibility

vs

Academia vs pharma

Pharma Company

BUSINESS DAY

Johnson & Johnson Will Make Clinical Data Available to Outside Researchers

By **KATIE THOMAS**   JAN. 14, 2015

the **YODA** PROJECT | Forging a unified scientific community

ABOUT   REQUEST   TRIALS   FAQS   LOG IN

Johnson & Johnson

Partnership with Johnson & Johnson Family of Companies

As of October 2014, the Yale University Open Data Access (YODA) Project is enabling scientists across the world to gain access to the company's clinical trial data assets. The goal is to balance data availability with an intention to promote strong scientific research and serve the public good. This effort will accelerate the movement of the clinical research enterprise toward more cooperative learning and sharing.

The YODA Project performs independent scientific reviews of investigator requests for Johnson & Johnson's pharmaceutical and medical device clinical trial data, including both full Clinical Study Reports and participant-level data. Johnson & Johnson has conferred on the YODA Project the authority to make decisions about the release of their clinical trial data. This

Policies & Procedures

Project Leadership

Steering Committee

Roles & Responsibilities

Data Holders

   Medtronic

   Johnson & Johnson

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Finland Offers a Unique Combination for Real-World Evidence Generation