ICPerMed
INTERNATIONAL CONSORTIUM

# *Which are the Ethical, Legal and Social Implications (ELSI) of Personalised Medicine (PM) research and implementation?*

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# Three questions to debate in this working group

- **1. The handling of incidental/ additional findings originating from molecular analysis.**
- **2. Informing the patient adequately; the issue of the tension between data-provision and the protection of a person's privacy.**
- **3. Tension between principles of evidence-based medicine and fast translation.**

# 1. The handling of incidental/ additional findings originating from molecular analysis.

**Discussion**

- **Definition needs to be clear (incidental/ additional vs research finding)**
- **Different policies in place ( return and no return)**
- **Tension between the researcher focus and the interest of research participants in learning about genetic information**

# 1. The handling of incidental/ additional findings originating from molecular analysis.

**Consensus**

- **There should be a policy in place that speaks to incidental findings.**
- **No return has the risk to not adequately respond to the information needs of participants.**
- **Ways to have patients participate in the exchange of research and/or individual results needs to be find and linked to evidence.**
- **Context specific policies: Children, newborn, relatives affected by genetic results.**
- **Returning results needs resources – return of results should be integrated in cost calculations.**

# 1. The handling of incidental/ additional findings originating from molecular analysis.

**Next Steps**

1. **Collect Experiences with the handling of incidental findings through**

- **Additional requirements by ethics review boards**
- **cases of incidental findings that were not reported and than a law cases filed**
- **cases of incidental findings with benefit to the individual**

2. **Data on follow up costs**

- **For informing patients / follow up diagnostics / benefits**
- **in contrast to empower patients and providers**

## 2. Informing the patient adequately; the issue of the tension between data-provision and the protection of a person's privacy.

**Discussion**

**Informed consent operates on two levels: informing the participant and legal basis**

**→Informing the participant needs to be tailored to context specific need ( patient level , different publics, family, gender, citizen)**

**→Legal basis: possibilities of other legal basis than consent for data processing**

**→New consent models: broad or dynamic consent**

## 2. Informing the patient adequately; the issue of the tension between data-provision and the protection of a person's privacy.

**Consensus:**

1. **Two way exchange – informing and getting feed back from those involved → getting patients/ participants involved in designing consent and information**
2. **Content needs to include: benefits (indidviual or collective), privacy, risk, time line (once or ongoing)**
3. **Information at group and population level (health literacy)**

## 2. Informing the patient adequately; the issue of the tension between data-provision and the protection of a person's privacy.

**Next steps:**

1. **Including participants in designing information and consenst**
2. **Collect Experiences with different consent models**

# 3. Tension between principles of evidence-based medicine and fast translation.

**Discussion:**

**Fast translation does not mean a lack of evidence**

**new ways of creating evidence**

**Consensus:**

**Still, in PM we treat patients without robust evidence for efficacy → risk for side effects/ costs**

## 3. Tension between principles of evidence-based medicine and fast translation.

**Next steps**

1. **Collect real world evidence about benefit/ risks and access**
   - **Needs adequate data collection (in a way to be evaluated)**
2. **Validation of diagnostic tools (IVD Regulation Requirements )**

# To be discussed....

# The promise of genomics

Anne Cambon-Thomsen

Meeting ICPerMed – 5-6/11/2019, Madrid

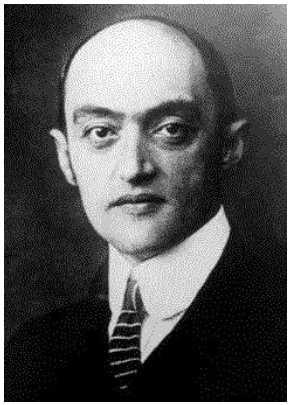
## The Cassandra Complex

"Ethicists" considered as being too negative or too late


**or**


"Just a minute!"

# Innovation & Values

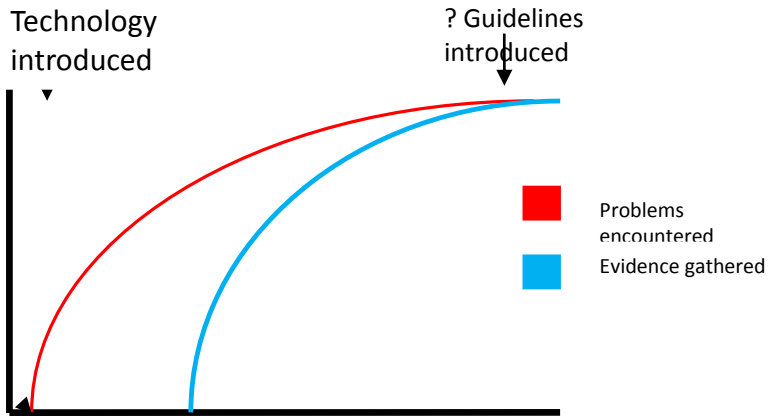


Schumpeter (1930): "Innovation changes

the values onto which the system is based"

Adapted from A Soulier and S. Leonard

## The evidentiary time-lag




Slide adapted from S. Leonard

# Blurring several limits

- Specific clinical question/ genome exploration
- Clinical care/ research
- Protocol of research/ database driven discovery
- Health information/ non health information
- Body elements / information
- Clinical utility /personal utility (curiosity)

## **Many** Ethical, Legal and Social Implications (ELSI) of PM research and implementation -

- Two main avenues:
- **Ethical and legal aspects regarding the collection, mining, access and use of data as well as on data security**
- **involvement of citizens and patients in decisions on these issues.**
- Two angles of analyses:
- **Fair access**
- **Technological aspect and identification of the benefits and the risks for each type of stakeholder.**