

Where there is a will, there is a way

Herman B.W.M. Koëter, M.Sc., D.Tox., ERT
Managing Director,

Orange House Partnership npo

and

Chairman,

Netherlands National Committee for the protection of animals
used for scientific purposes

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Replace

Reduce

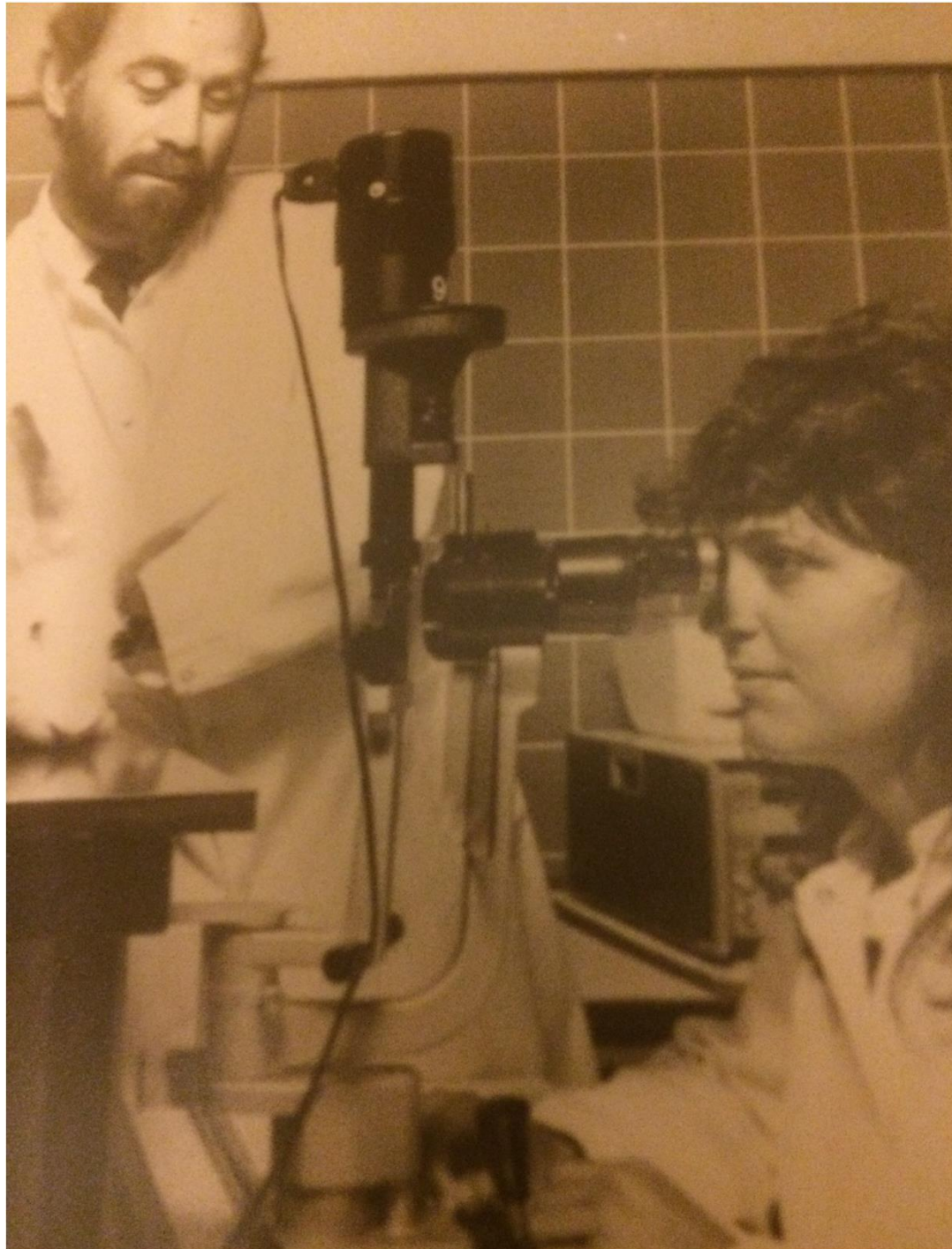
Refine

Traditional concept of replacement



Replace, Reduce, Refine





Achievement
since 1960s:

1% of animals
used in regulatory
testing

Categories of “scientific purposes” (Dir/ 2010/63/EU)

- Educational and professional training,
- Regulatory safety testing,
- Routine production testing, including
 - Quality control
 - Efficacy and tolerance testing
- Fundamental research,
- Translational and applied research

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(d) any information that might indicate non-compliance.

3. Inspections shall be carried out on at least one third of the users each year in accordance with the risk analysis referred to in paragraph 2. However, breeders, suppliers and users of non-human primates shall be inspected at least once a year.

4. An appropriate proportion of the inspections shall be carried out without prior warning.

5. Records of all inspections shall be kept for at least 5 years.

Article 35

Controls of Member State inspections

1. The Commission shall, when there is due reason for concern, taking into account, inter alia, the proportion of inspections carried out without prior warning, undertake controls of the infrastructure and operation of national inspections in Member States.

2. The Member State in the territory of which the control referred to in paragraph 1 is being carried out shall give all necessary assistance to the experts of the Commission in carrying out their duties. The Commission shall inform the competent authority of the Member State concerned of the results of the control.

3. The competent authority of the Member State concerned shall take measures to take account of the results of the control referred to in paragraph 1.

(b) a non-technical project summary; and

(c) information on the elements set out in Annex VI.

2. Member States may waive the requirement in paragraph 1(b) for projects referred to in Article 42(1).

Article 38

Project evaluation

1. The project evaluation shall be performed with a degree of detail appropriate for the type of project and shall verify that the project meets the following criteria:

(a) the project is justified from a scientific or educational point of view or required by law;

(b) the purposes of the project justify the use of animals; and

(c) the project is designed so as to enable procedures to be carried out in the most humane and environmentally sensitive manner possible.

2. The project evaluation shall consist in particular of the following:

(a) an evaluation of the objectives of the project, the predicted scientific benefits or educational value;

(b) an assessment of the compliance of the project with the requirement of replacement, reduction and refinement;

(c) an assessment and assignment of the classification of the severity of procedures;

Dir/2010/63/EU:

“The purpose of the project justifies the use of animals”

- There are no harmonised criteria for this judgement, and there never will be
- The composition of competent authorities (that evaluate and authorize projects involving animals) varies considerably, both in number of members and in level/width of expertise
- Guidance like synthesis of evidence and codes of practice are useful but do not truly address science versus ethical values

End of story?

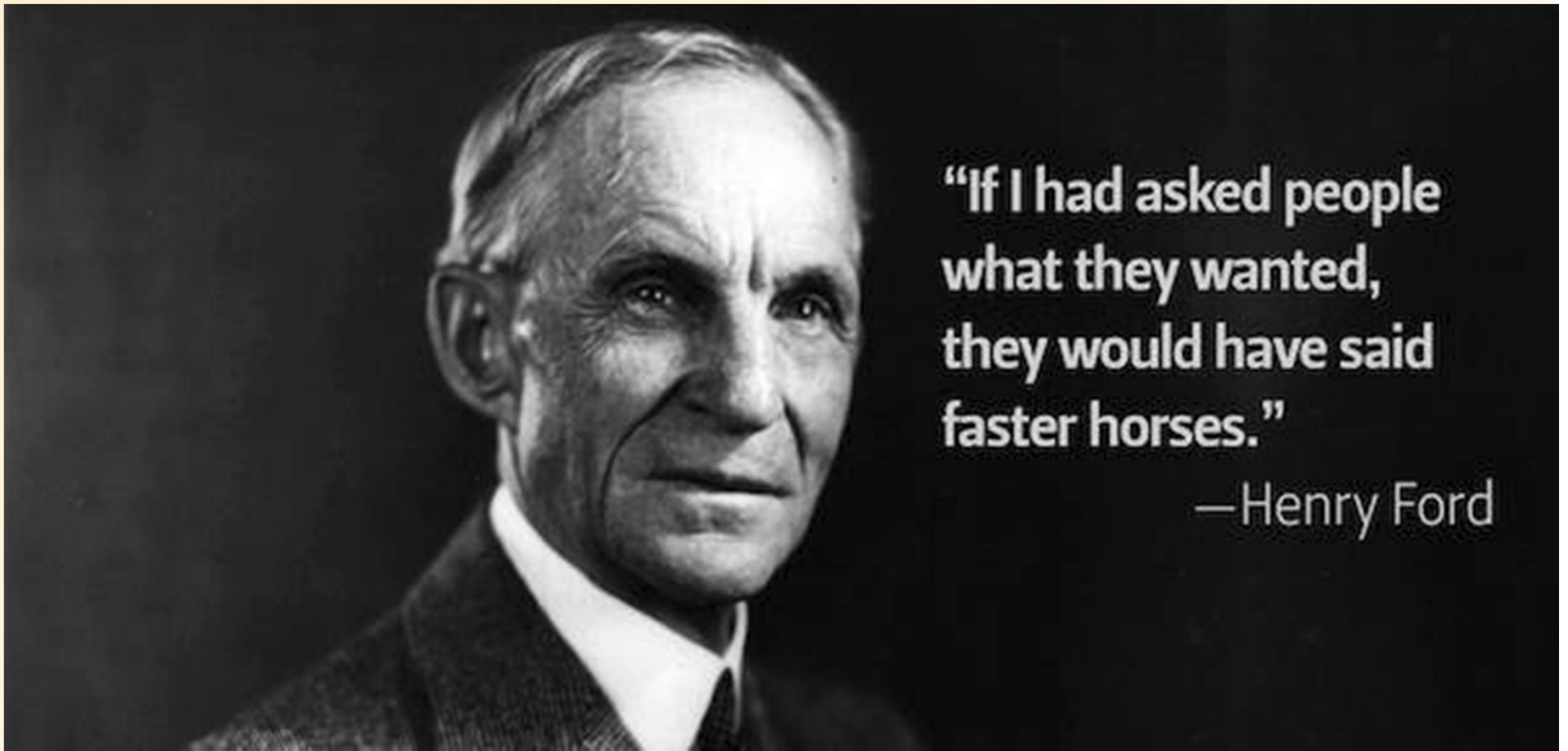


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MY POINT ON THE HORIZON

**A true transition to scientific
progress and innovation without
the need for animal studies**

MY POINT ON THE HORIZON



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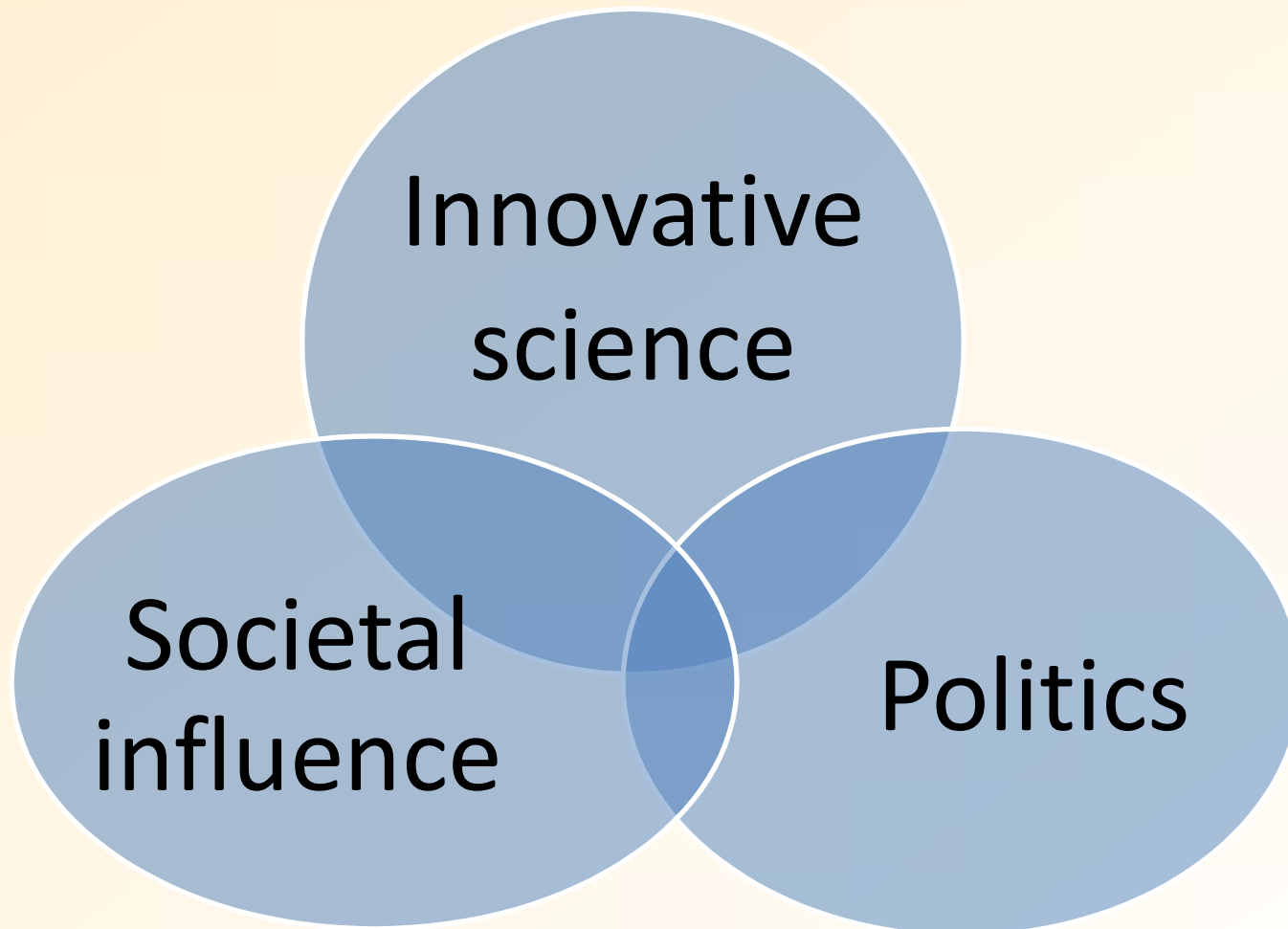
Is a transition a realistic proposition?



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Transition to animal free research



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**“There are many roads
that lead to Rome”**

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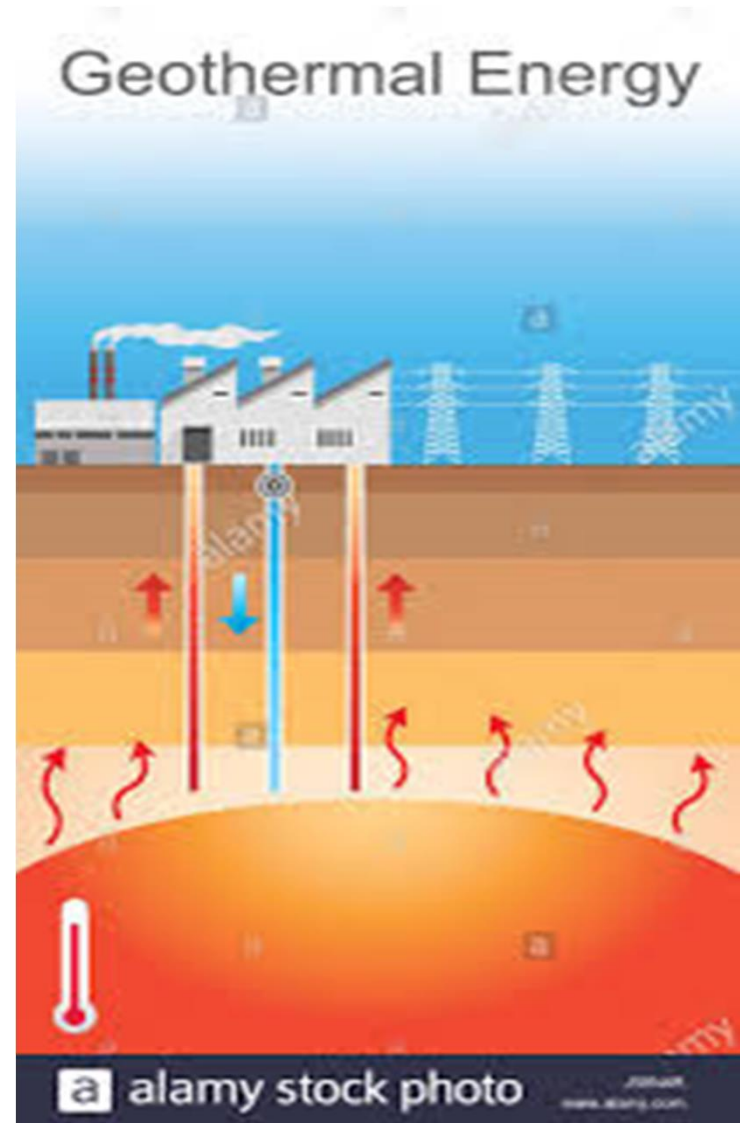
Renewable energy



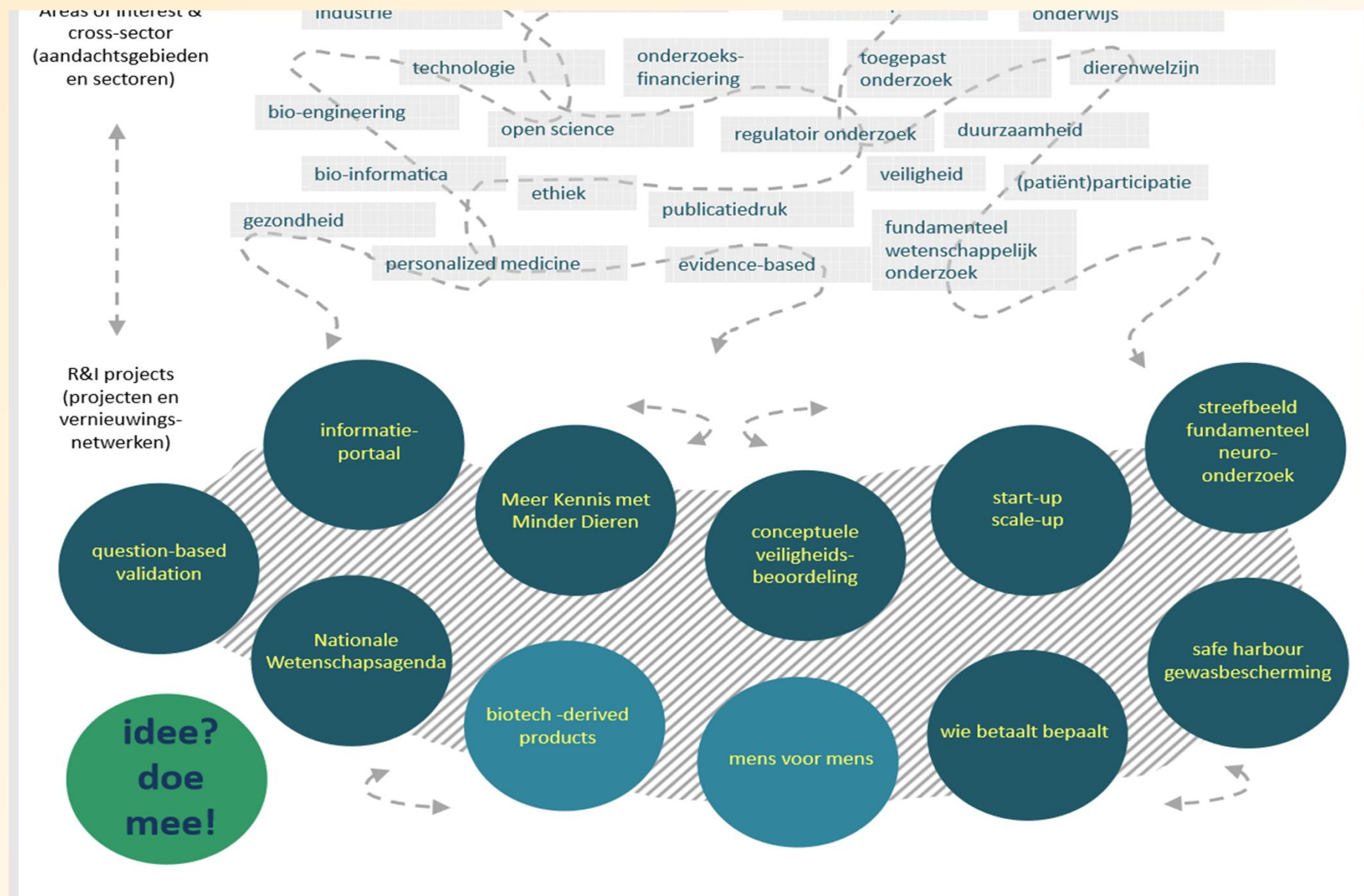
Renewable energy



Renewable energy



Chaos?



Visualization of transition



Essential factors of succes

- Governmental support, direction and supervision
- In cooperation with the private sector
- In cooperation with the public and private sector in other countries
- In cooperation with NGOs
- With and by the scientific society
- With financial support of all parties
- In close contact with society

The transition to fully renewable energy **will be** successful once various paths and approaches are combined.

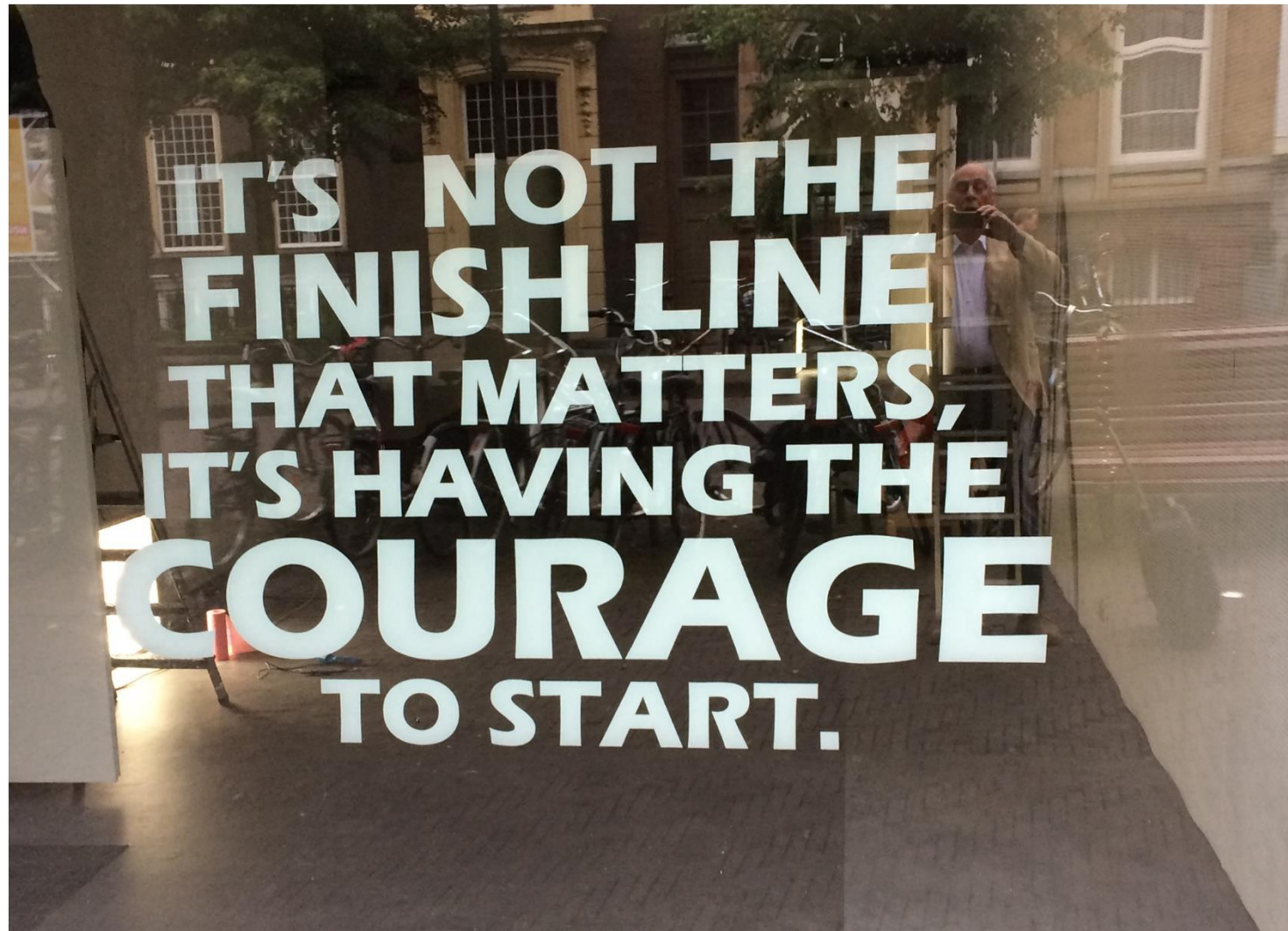
Similary, the transition to scientific research without experimental animals will be achieved by following and combining all promising pathways

Today



Tomorrow







“Aim higher and wider”

Motto of the 11th World
Scouts Jamboree,
Marathon, Greece, 1963

Paving the road towards transition

- Work together with colleague scientists as it will strengthen support
- Openness and transparency are key as they bring trust
- Roadmaps aiming at animal free research will never fail: whatever the outcome it always will be a learning process and the starting point of the next attempt

Development of transition targets (road maps)

- List current **key research issues and objectives** of the respective scientific (sub)domains
- Define the **strength and weaknesses** of the traditional methodologies, contributing to the achievement of the original goal
- Collect available **3R activities** in the selected (sub)domain (investment in creative and promising animal-free innovations)
- Define specific **research targets** for a set time period (e.g. 10 year)

Development of transition targets (road maps)

- **Apply animal-free approaches** and innovations that are currently available or expected to become available in the foreseeable future: include innovations that are used in related domains
- Provide **indications of the successfulness** (trends) in finding animal-free transition targets
- **Document yearly capacity and resources invested in 3R activities** as a percentage of the total capacity and resources (to be used to contribute to the ranking of the (sub)domain with respect to animal welfare
- Document **progress** .

Development of transition targets (road maps)

- Don't lose sight of the **original research goal(s)**,
- Introduce regularly focussed **brainstorm sessions**, involving experts from unrelated research domains,
- Involve **young scientists** with a clean slate and an unprejudiced, open mind,
- Seek **national and international cooperation**
- Teach as well as learn to **think outside your own comfort zone.**