Erasmus MC
University Medical Center Rotterdam

Nice to meet? Ethical issues surrounding efforts to facilitate early access to investigational drugs

Eline M. Bunnik

NEC Forum
The Hague, 11th May 2016

NWO
Nederlandse Organisatie voor Wetenschappelijk Onderzoek

Responsible Innovation
Maatschappelijk Verantwoord Innoveren

Conditions for expanded access

- serious/life-threatening disease
- no alternative
- potential for benefit

- not eligible for trial participation

- approval from drug regulatory authority/inspectorate
- approval from IRB

Erasmus MC

2

Nederlandse Organisatie voor Wetenschappelijk Onderzoek

Responsible Innovation
Maatschappelijk Verantwoord Innoveren

Research project: 'Nice to meet? Meeting unmet medical needs: a social innovation to facilitate early access to investigational drugs' (2015-2017)

Responsible Innovation (MVI) programme at the Netherlands Organisation for Scientific Research (NWO), to stimulate research on ethical and societal issues surrounding an innovative product or service during the design and development process.

Top sector: Life Sciences & Health

Erasmus MC

3

Interview study: medical doctors

- Lack of knowledge/experience
- Dissatisfaction with process
- Uncertain outcome
  - inspectorate
  - pharmaceutical company
  - funding

Low uptake in the Netherlands

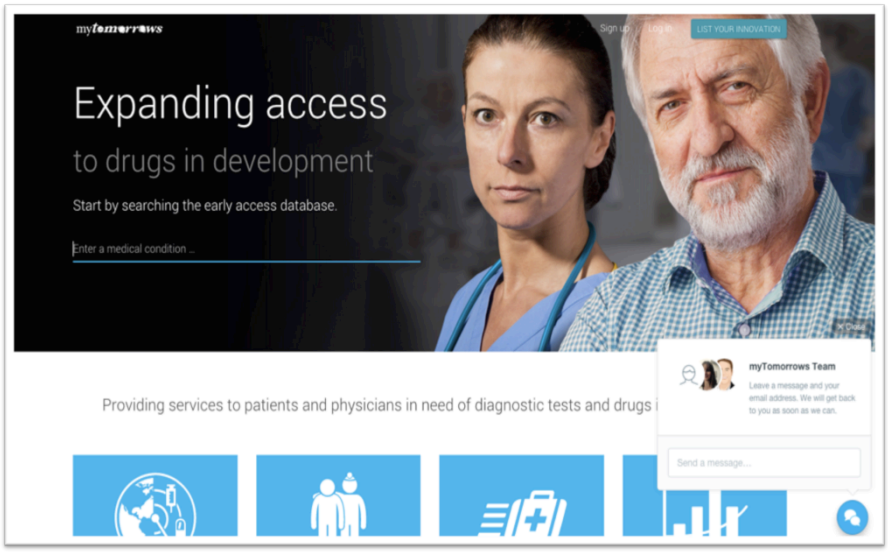
Erasmus MC

4

Right to Try movement in USA

Erasmus MC

5



Erasmus MC

myTomorrows

Erasmus MC

7

From an exemption to a default option?

"The named patient programme was intended as a valve in the system (…) For that one patient who would otherwise have to wait until the entire system has made sure that [the drug] works for the whole group. (…) That would not be reasonable. (…) But it would be inconvenient if this exception would become the rule."

Erasmus MC

8

"It is very dangerous to offer false hope to patients who have run out of options, for a fee." (W. Wind, NPCF, 2013)

mytomorrows

Erasmus MC

9

Our research project

Aim: to develop an ethical framework for a responsible design of efforts to facilitate early access to investigational drugs

Approach:

- Interviews with stakeholders (n = 32) in the Netherlands
- Qualitative (and quantitative) studies of patients' views in the Netherlands, US and Turkey (focus groups and survey)
- Qualitative (and quantitative) studies of physicians' views in the Netherlands, US and Turkey (interviews and survey)

Erasmus MC

10

Acknowledgements

Project group:
Dr. Nikkie Aarts
Prof.dr. Suzanne van de Vathorst
Dr. Loes Visser

For further questions: e.bunnik@erasmusmc.nl

NWO
Nederlandse Organisatie voor Wetenschappelijk Onderzoek

Erasmus MC

11