PREFER

Patient Preferences in Benefit-Risk Assessments during the Drug Life Cycle

Version 1.1 May 2017

Disclaimer: This presentation and its contents reflects the view of the presenter and not the view of PREFER, IMI, the European Union or EFPIA.

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About the PREFER project

The Patient Preferences in Benefit-Risk Assessments during the Drug Life Cycle (PREFER) is a five year project that has received funding from the **Innovative Medicines Initiative** 2 Joint Undertaking under grant agreement No 115966. This Joint Undertaking receives support from the European Union's **Horizon 2020** research and innovation programme and **EFPIA**.

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Unmet need PREFER addresses

Currently a lack of understanding of how patient perspectives on benefits and risks can best inform decision-making.

PREFER aims to identify, characterise, and apply preference elicitation methods in all stages of drug life cycle.

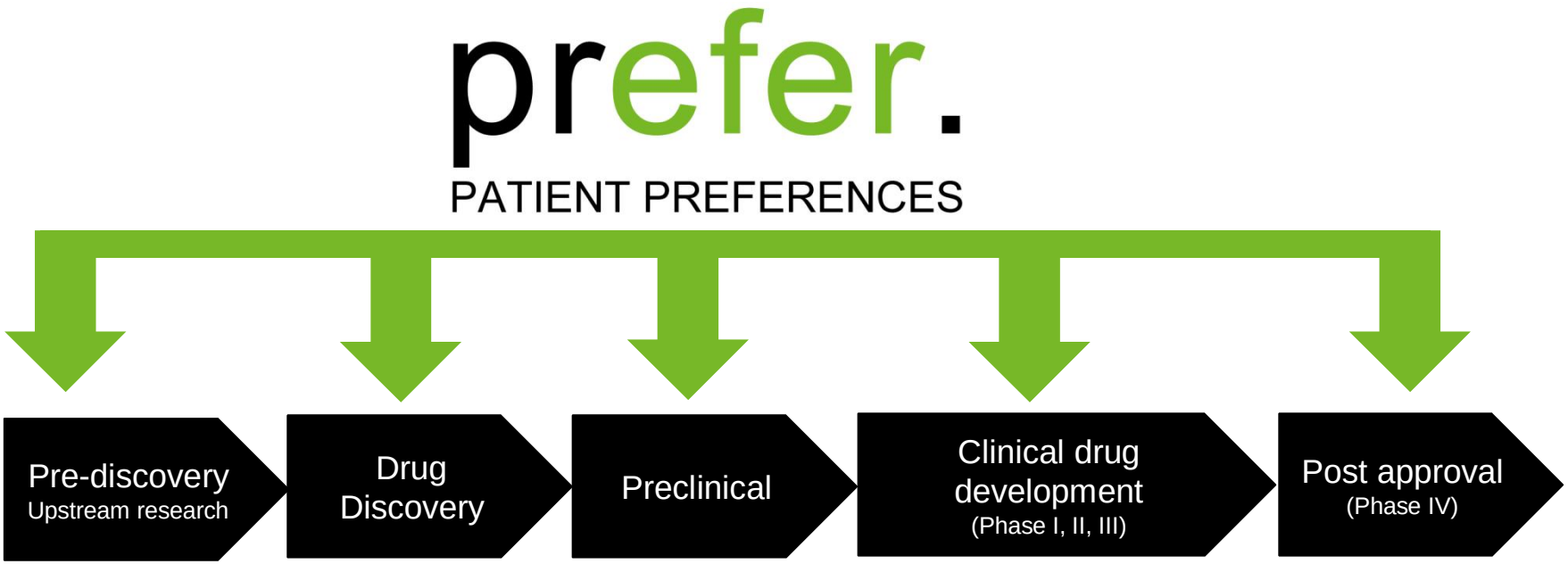
PREFER project goals

- Establish **recommendations** to **support development of guidelines** for
  - Industry
  - Regulatory Authorities
  - HTA bodies & payers
- **on how and when to include patient preferences** on benefits and risks of medical products.

PREFER approach

- **Run patient preference studies** in academic and industry settings.
- **Provide a better understanding** of the best-practice approach to patient-preference studies.
- **Show how patient preference studies can support decision** making for industry, regulators and HTA bodies.

Seeks methods for all stages



Public-private partnership

- **Coordinator:** Uppsala University (Mats Hansson)
- **Project leader:** Novartis Pharma (Conny Berlin)
  - 10 Academic research institutions
  - 4 Patient organisations
  - 1 Health Technology Assessment body
  - 2 SMEs (small and medium sized enterprises)
  - 16 Pharmaceutical companies

PREFER partners

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Organisation of PREFER

- Shared leadership at all levels
  - From leadership, to work packages to tasks
- Stakeholder partners & advisory groups
  - Patient Advisory Group
  - HTA and Payers Advisory Group
  - Regulatory Advisory Group
- Scientific & Ethics advisory boards

Stakeholder advisory groups

PATIENTS
4 partners

EUROPEAN CANCER PATIENT COALITION

EPF European Patients Forum

International Alliance of Patients' Organizations

Muscular Dystrophy UK
Fighting muscle-wasting conditions

HTA AND PAYERS
1 partner, 5 external advisors

KCE
Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

Ludwig Boltzmann Institut
Health Technology Assessment

Gemeinsamer Bundesausschuss

CADTH

INAMI

eunethta

REGULATORS
External advisors

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Committee for Medicinal Products for Human Use (CHMP)

Scientific Advice Working Party (SAWP)

Committee for Orphan Medicinal Products (COMP)

FDA
Center for Biologics Evaluation and Research

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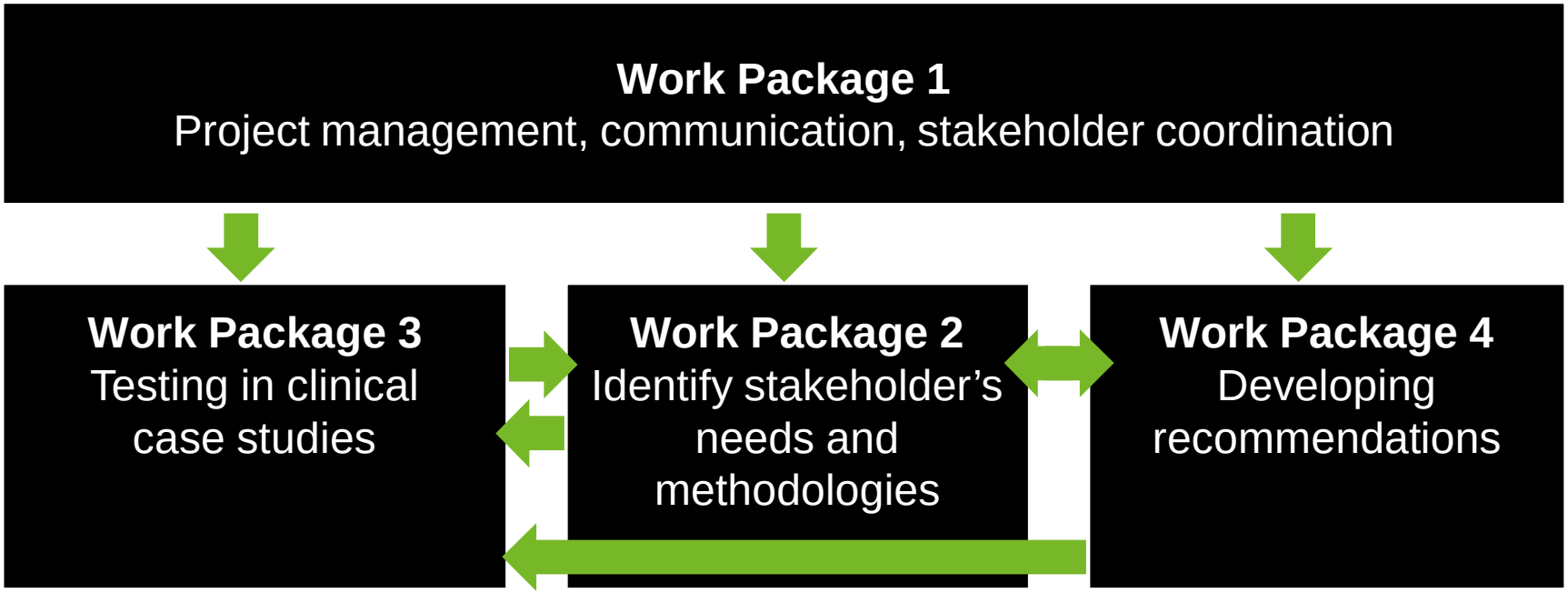
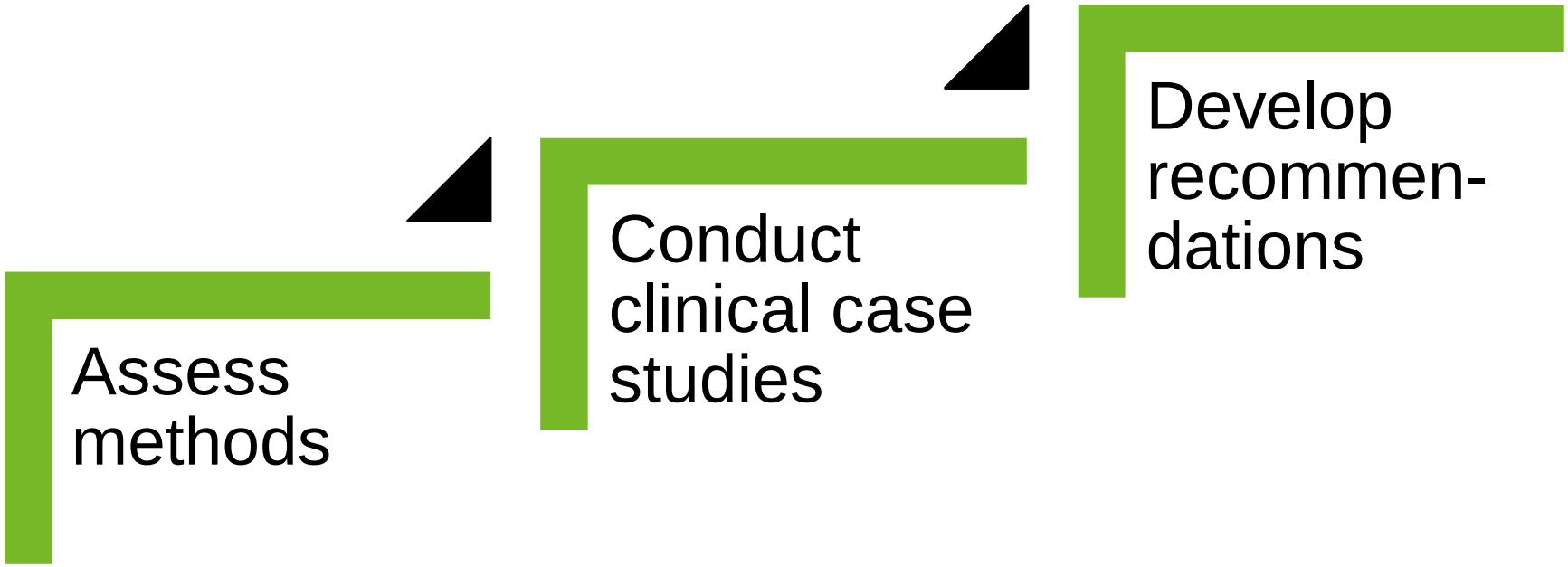
PREFER work packages



Stepwise approach



1: Assessing methods

WP 2

- Literature review
- Interviews and focus group meetings with
  - patient organisations & patients
  - physicians
  - regulatory authorities
  - health technology assessment bodies & payers
  - industry experts
  - & academics

  on their key concerns, needs, expectations and desires on the assessment and use of patient preferences.

2: Clinical case studies

WP 3

Patient preference studies to be conducted in three disease areas where **patients** and **clinical research partners** already provide expertise:

- Cancer
- Rheumatoid arthritis
- Neuromuscular disorders

Partners from the **pharmaceutical industry** will provide additional patient preference studies to cover disease areas from the companies' portfolio.

3: Recommendations

WP 4

- **Mid-2019:** draft recommendations to be available, testing in other disease areas and decision points by stakeholder advisory groups.
- **Mid-2021:** refined draft recommendations to be available
- **Autumn 2021:** Final recommendations to be presented.

In summary, PREFER

- Will develop evidence-based recommendations to guide industry, Regulatory Authorities, HTA bodies, reimbursement agencies
- Carried out by a diverse consortium that involves stakeholders: both as partners and advisors

More information

www.imi-prefer.eu