Knowledge repository to enable patient-focus medicine development

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14.01.2015 • IMI webinar

Need for public-private collaboration

- Funding
- Collaboration
- Standardization
- Trust

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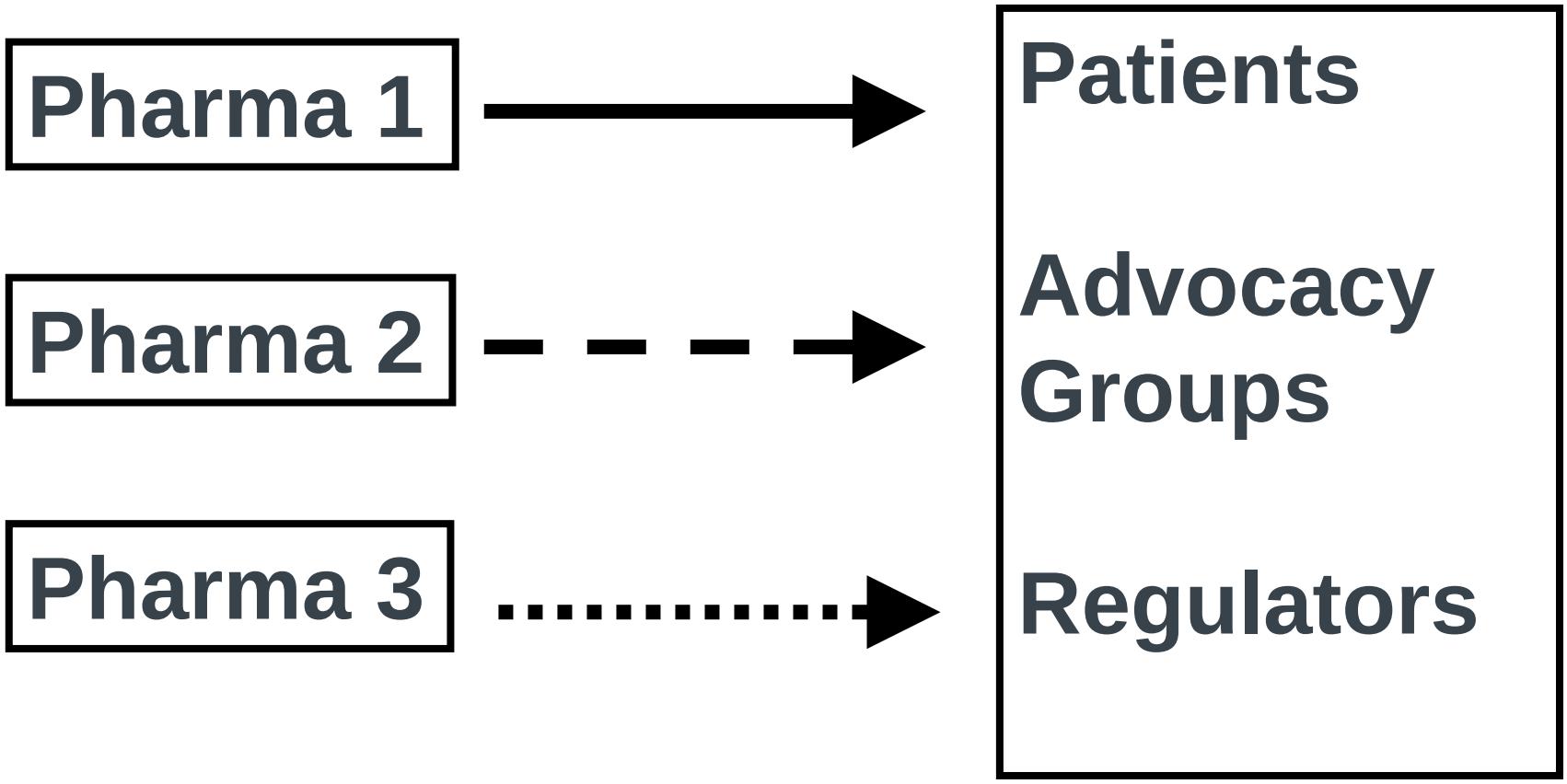
Objectives of the full project

- **Opportunity:**
  - There is currently no uniform process or understanding of capabilities of stakeholders to enable industry to engage patients in the drug discovery & development process
- **Objective:**
  - Develop and deliver a Patient Inspired Knowledge Hub (PIKH) that enables sharing of information and capabilities with and by users from patient groups, regulators, health authorities, academic medical centers, scientific organizations and industry.
- **Overall Goal:**
  - Make medicines development relevant to the real world patient and more efficient through systematic patient involvement.
  - Be the search tool for current global capabilities of stakeholders based on a defined patient engagement need which is accepted and continually refined by all stakeholders.

Today



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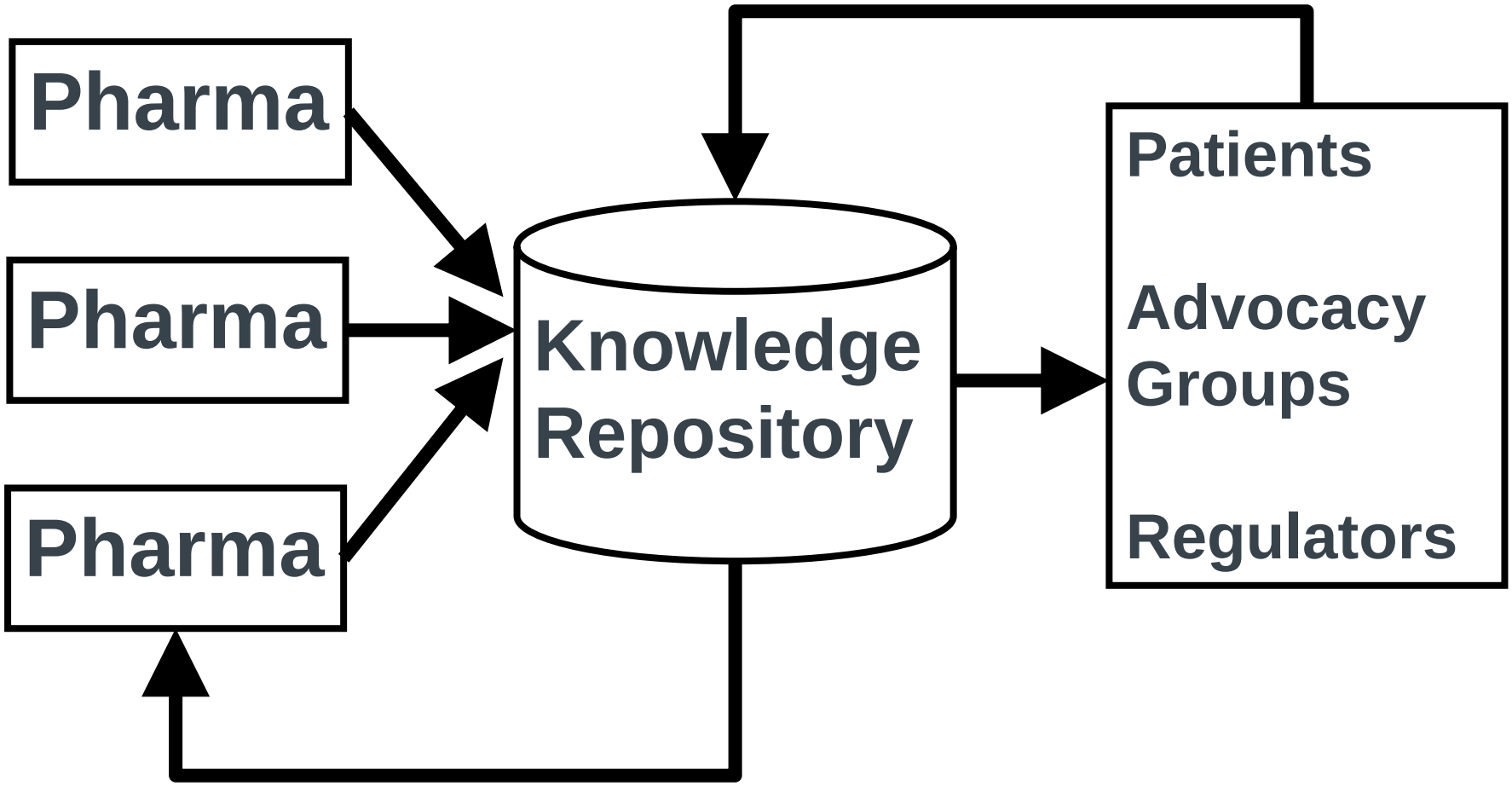
Future



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Pre-competitive nature

- Best possible dialogue with patients is a key ingredient of developing products that will win in a competitive market place.

- It’s the right thing to do for the patients

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Expected impact on the R&D process

1. **Holistic understanding of the patient life context-**
    - includes co-morbidities, reaction to pricing/co-pays, Health Care Systems in which they participate, barriers to adherence, patient trade offs and decision making
2. **Health Technology Assessments** for payer acceptability
3. **Patient's own Benefit-Risk assessment** of treatment outcomes versus their disease/situation
    - may result in potential prospective subgroup identification for regulatory approval
4. **Packaging design/market image-** cultural and regional acceptability is key
5. **Endpoint selection** - what endpoints and messages about products resonate with patients and meet their expectations?
6. **Clinical trial design/ protocol-** feasibility assessment; how many visits, tests, specialist visits
7. **Clinical trial recruitment optimization**—(plus diversity focus) ; input on standards, communications before, during and after trials; within trial patient communities
8. **Health Literate Patient labeling-**
9. **Patient education materials and health care apps- throughout life cycle**

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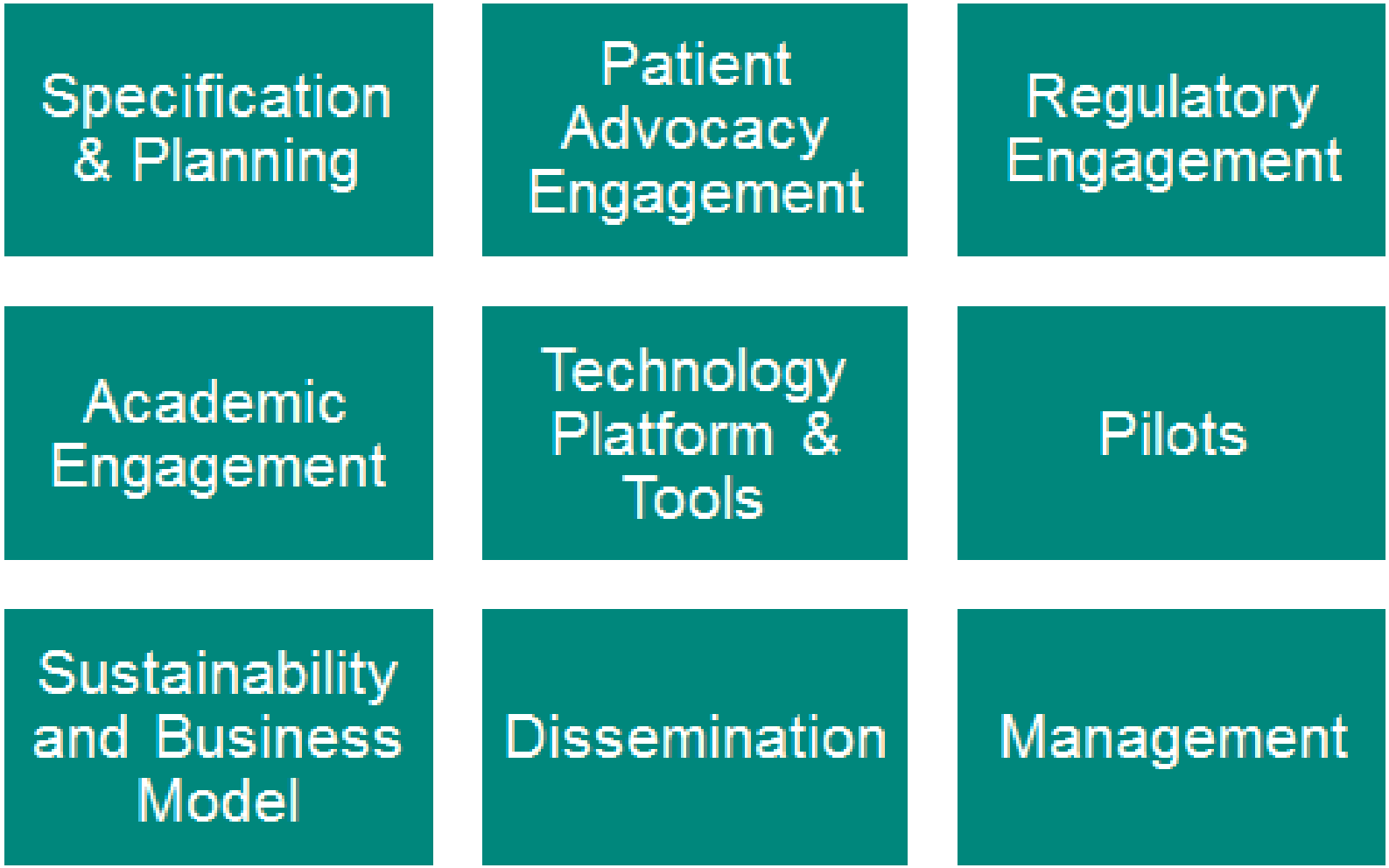
Suggested architecture of the project



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Expected contributions of the applicants

- **Domain Expertise**
  - Clinical Knowledge
  - Regulatory Affairs
  - Patient Advocacy
  - Many more
- **Functional Expertise**
  - Patient Focus Groups
  - Running pilots in settings of care
  - User Centred Design
  - Business Process/Workflow Modelling
- **Service Provider/Execution**
  - Product Management
  - Project Management
  - Technology Development
  - Protocol Development
  - Integrator
  - Commercialization and Business Development
  - Many more

Expected (in kind) contributions of EFPIA members

- Domain Expertise
  - Drug Discovery all the way to Commercial
  - Support services (scientific modelling, sales, supply chain, etc)
  - CIO & CMO organizations
- Network Access
  - Industry
  - Academia
- Execution (FTE)
  - Product development
  - Project management
  - Domain expertise (Clinical, regulatory, commercial, etc)
- Existing Assets
  - Technology and Platform
  - Knowledge, Protocols, Tools, etc

What's in it for you?

- Advance the state of Science directly and indirectly
- Translate research and academic findings into practice
- Developed bio-informatics platforms and tools
- Create a better dialogue between patients and industry
- Provide transparency into menu of best practices
- Leverage this project to integrate other Patient centred initiatives
- A place for stakeholders to gather and have an exchange
- Practical experience with working multiple pharma companies under one roof
- Funds to finance SME growth
- Build infrastructure that will lead to commercialization opportunities

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Key deliverables of the full project

- Identifying the appropriate points in time to interact with patients for development of medicine, including: risks and benefits of interactions, required capabilities, anticipated enabling changes in regulatory affairs and more.

- Standardizing a framework to be used for patient engagement in medicine development.

- Providing the ecosystem and mechanisms for stakeholders, for example pharmaceutical companies and patient advocacy groups to discuss and share frameworks, methods and knowledge.

Questions?

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