



European Federation of Pharmaceutical
Industries and Associations

BIAC Meeting on ICT in Healthcare

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EFPIA Task Force on Electronic Health Records

Potential Pathways for Pharma Industry

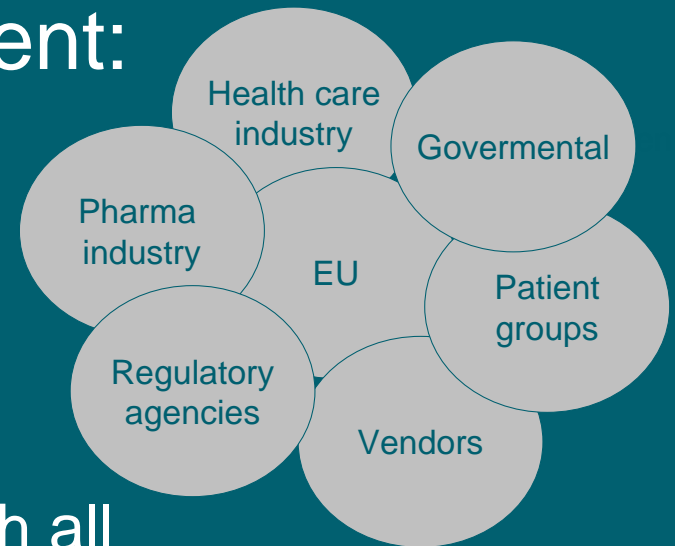
- Pharma industry involvement:

- Reactive scenario

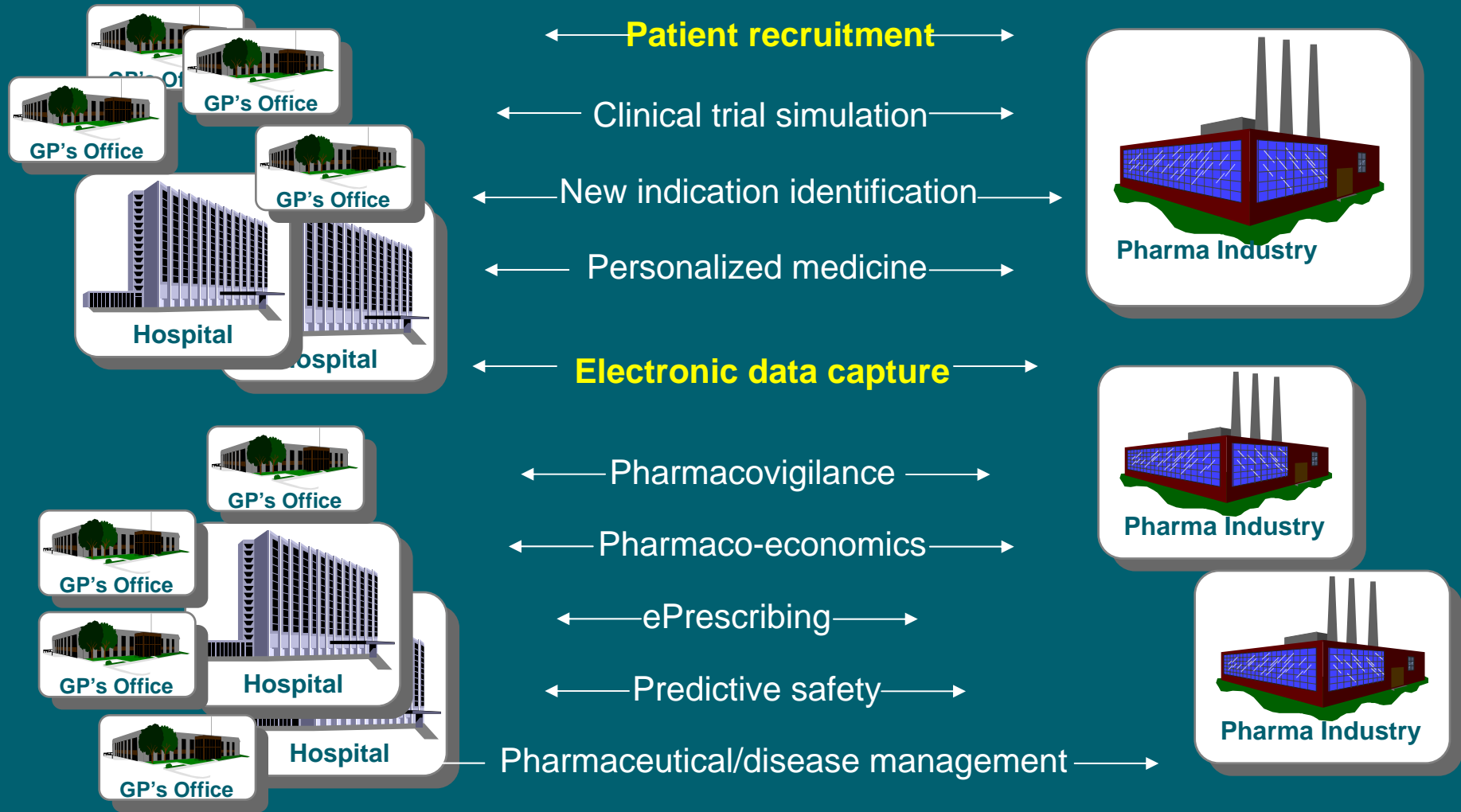
- “wait and see”

- Proactive scenario

- Industry acts to promote collaboration & interaction with all stakeholders to enhance progress and create value



Clinical Care and Clinical Research



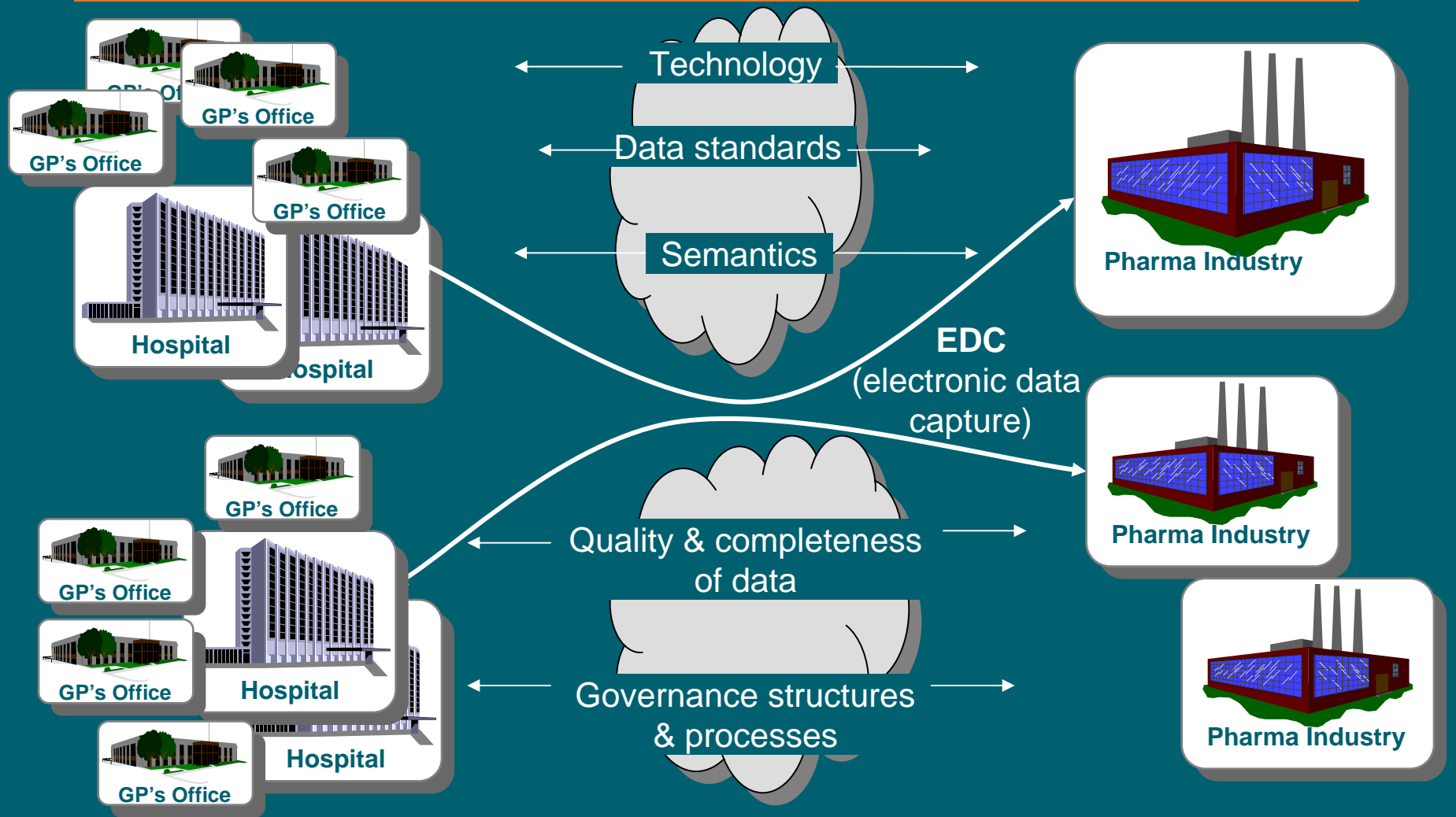
EHR Workshop

- “Primary and secondary use of EHR: Enhancing clinical research” (Brussels 11-12th Oct. 2007)
- Organizing Committee
 - European Commission: DG Information Society & Media
 - European Federation of Pharmaceutical Industries & Associations (EFPIA)
 - European Institute for Health Records (EuroRec)
 - Clinical Care, IT Vendors, Legal
- Workstreams
 - Interoperability
 - Interaction models and processes
 - Legal & privacy issues

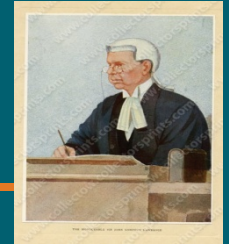
<http://www.eurorec.org/EHRWorkshop/model.cfm?selection=model&actief=EHRWorkshop>

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2 separate “electronic” worlds....



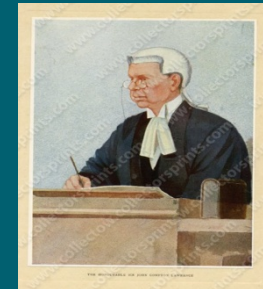
The Legal Basics



- Directive 95/46/EC on Data Protection
 - “Member States shall **prohibit** the processing of personal dataconcerning health or sex life.” Article 8 (1)
 - ‘Personal data’ means all personal identifiable data
 - ‘Processing’ means more than collection – it includes any operation on the data
- Exceptions:
 - Consent (freely given, specific, informed) or in vital interests of subject
 - Processing of (medical) data by health professionals
 - required and takes place for **specific purpose** of preventative medicine, medical diagnosis, provision of care or treatment or the management of health care services
 - Substantial public interest exemptions: e.g. public health social protection

Challenges for Primary & Secondary Use

- The fundamental distinction being made between primary & secondary use for medical research
- EHR data – individual vs. aggregated
- Who aggregates and for what purposes?
 - Third party involvement (public, private, academic)
- Patient right of privacy:
 - Anonymisation vs. pseudonymisation
- Data ownership
 - Physical, Legal, ownership
 - Intellectual property issues

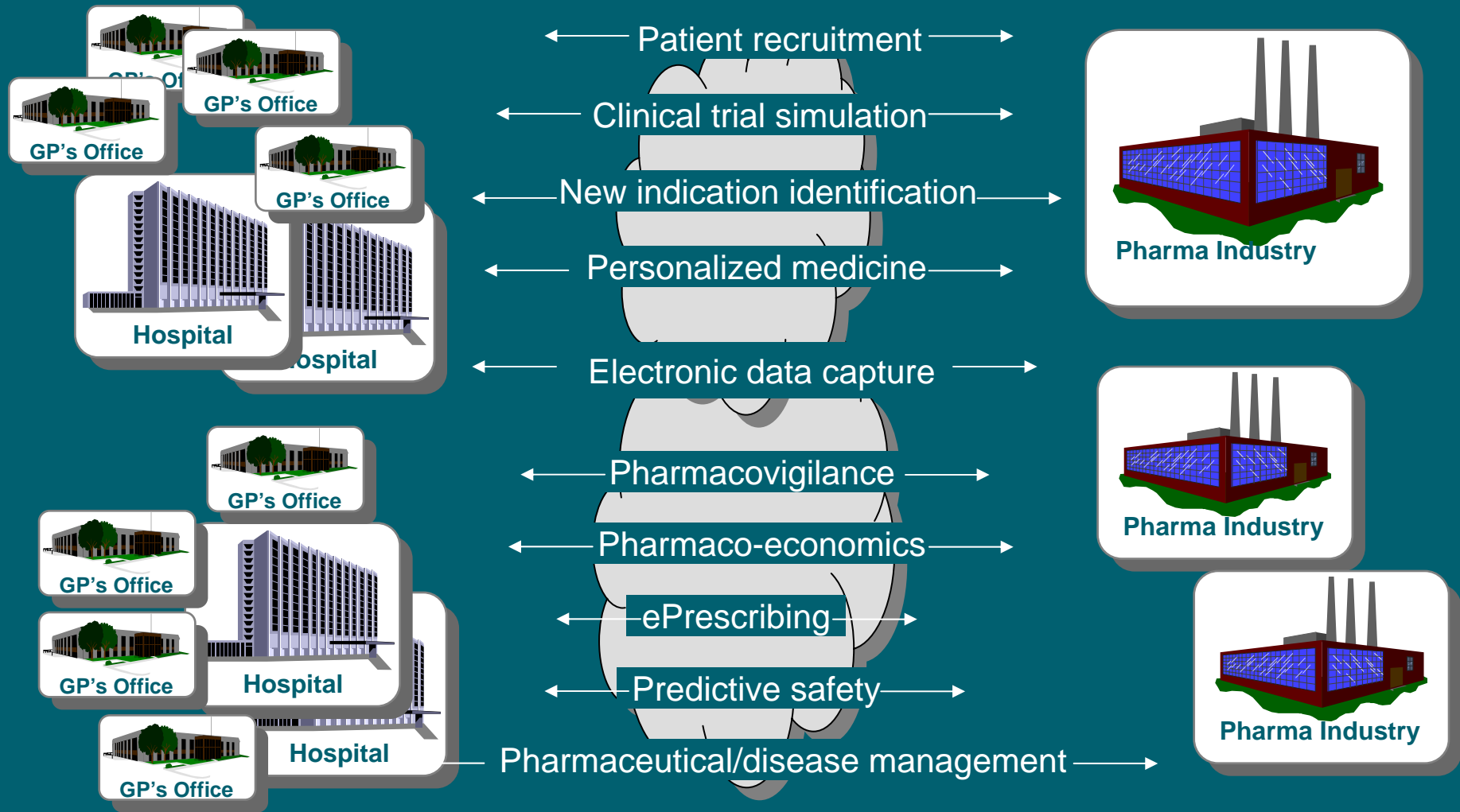


Legal Stream Key Recommendations

- Actively seek to clarify legislation relating to use of EHR data for medical research
- Define “model contract terms” for third party data aggregation service providers
- Guidance on use of privacy enhancing technologies (PET)
- Transparency and cooperation across EU member states to support harmonization on interpretations of data protection legislation

Clinical Care and Clinical Research

2 Interoperable “electronic” worlds....



Reference Material

EFPIA – EHR Task Force Participants

- Isabelle de ZEGHER *Novartis (Chairperson)*
- Bernard FERRE *EFPIA*
- Mia BENGSTROM *Pharma Industry Finland*
- Bob BIRMINGHAM *J & J – liaison with PhRMA ERES & PhRMA HIT*
- Frank JENSEN *Lundbeck*
- Pierre-Yves LASTIC *Sanofi Aventis, CDISC Board member*
- Marc PEETERS *Roche – Coordinator for IMI*
- Jean SAMUEL *Pfizer*
- Stan SNOWBALL *MSD*
- Greg STADLER *Eli Lilly*
- Mats SUNDGREN *AstraZeneca*
- Rob THWAITES *GSK*

EFPIA – EHR Task force - Objectives

- Build a common understanding of what is EHR, its potential & challenges for clinical research (EU focus)
- Define EFPIA consolidated position related to EHR and identify 2 or 3 critical initiatives to push forward
- Liaise with
 - European Commission in the context of eHealth initiative
 - Similar working group in the US (PhRMA HIT working group)
- Support/push data standardization activities related to EHR in clinical care in Europe => second priority
- Build business case: why would we invest into EHR integration ?

EFPIA – EHR Task Force Milestones*

- Common understanding on EHR usage, potential & challenges (organizational, technical, legal) for clinical research
- Understanding on key stakeholders & interaction model around EHR usage
 - Focus on decisions makers and possibility to influence
 - Role of software vendors and evaluation of potential partnership
- FINAL deliverable: Position paper with
 - Business case
 - Identification of 2 or 3 critical areas of highest interest in Europe
 - Recommendation to next steps

** 1 Year Milestones*

Electronic Health Record - Definition^(*)

- Repository of information regarding the health status of a subject of care
 - In computer processable form
 - Stored and transmitted securely
 - Accessible by multiple authorized users
 - Having a standardized or commonly agreed logical information model independent of EHR systems
 - Whose primary purpose is the support of continuing, efficient and quality integrated health care
- Contains information which is retrospective, current and prospective

^(*) After ISO/TR 20514: Health Informatics- Electronic health record – Definition, Scope and Context