The Impact of the Re-use of EHR Data
- A Pharmaceutical Industry Perspective -

Andreas Schmidt, Pharma Development
Mats Sundgren, Global Clinical Development

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Context

• The primary purpose of EHR is to improve the quality and efficiency of patient care. As such EHR’s are created and held according to professional and legal obligations of confidentiality.

• However, EHR information also holds huge value for additional purposes including medical research which in return can support healthcare.

• Key challenges therefore include the development of appropriate mechanism by which an appropriate balance can be achieved between data protection on the one hand and a more optimized use of EHRs.
Time for Action

Innovation in medical technologies is about to take off
(R Lager, MIT)

Medicine “is likely to be transformed by the introduction of EHR that can be turned into searchable medical databases, providing a ‘smart grid’ for medicine that will not only improve clinical practice but also help to revive drugs research”
(The Economist, April 16th 2009)
Pharmaceutical Drug Development

*The magnitude*…

<table>
<thead>
<tr>
<th></th>
<th>Number</th>
<th>Countries</th>
<th>Europe</th>
<th>Sponsors</th>
<th>Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Clinical Studies (July '09)*</td>
<td>759</td>
<td>75</td>
<td></td>
<td>359</td>
<td>231'502</td>
</tr>
<tr>
<td>Total Trials Listed</td>
<td>&gt;76,000</td>
<td>169</td>
<td>&gt;37,000</td>
<td></td>
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<tr>
<td>Ongoing Trials</td>
<td>7'113</td>
<td></td>
<td></td>
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<tr>
<td>Investigators (2007)</td>
<td>23'000</td>
<td>4'200</td>
<td></td>
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<table>
<thead>
<tr>
<th></th>
<th>EFPIA</th>
<th>US</th>
<th>Global '08</th>
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<tbody>
<tr>
<td>Spending R&amp;D (2007)</td>
<td>24.8 bil€</td>
<td>25.7 bil€</td>
<td>≈ 62.5 bil€</td>
</tr>
<tr>
<td>Growth rate</td>
<td>5.1%</td>
<td>6.7%</td>
<td>+85% (01)</td>
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<thead>
<tr>
<th></th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
</tr>
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<tbody>
<tr>
<td>Average cost per patient (2006)</td>
<td>$10'200</td>
<td>$7'800</td>
<td>$7'300</td>
</tr>
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</table>

* BioPharm Insight, August 2009
Pharmaceutical Drug Development

The magnitude....

Conclusion

Assuming an efficiency gain of 10% through the re-use of EHR patient data for drug development research, the total savings for Pharma alone should be substantial.
Electronic Health Records

Some of the Issues....

The healthcare information environment is fragmented by lack of legal and technical standards, cost effective platforms, and sustainable business models. This has hindered medical research and clinical development:

1. Protocols are often designed without sufficient understanding of real patient populations; design is sub-optimal

2. Information on the location of patients meeting admission criteria is incomplete, slowing patient recruitment

3. Recollecting patient data for clinical trials instead of using existing EHRs compromises cost-efficiency

4. The present situation requires researchers to carry out studies in an isolated fashion in many locations rather than utilizing a unified approach across the different research centers (economies of scale).
A Changing Environment in EU & US
New Opportunities... (I)

• Increased focus on HIT
  – The European Seventh Framework Programme (FP7) for research and technological development
  – “Health Information Technology for Economic and Clinical Health Act” (HITECH Act), part of the American Recovery and Reinvestment Act of 2009

• EHR technologies becoming more mature
  – E.g., a survey (1) evaluating 15 EHR vendor products’ functionalities across the identified 14 clinical research use case categories found
    • All 10 replying vendors fully or partially met 8 use case categories
    • 9 replying vendors fully or partially met 3 additional use case categories
    • 8 replying vendors fully or partially met 2 additional use case categories.

(1) DAIJIN KIM et al
A Changing Environment in EU & US
New Opportunities...(II)

- Standardization efforts and nomenclature models are moving forward e.g.,
  - EHRCR (Electronic Health Records for Clinical Research) Working Group is sponsored by eClinical Forum and PhRMA EDC/eSource Task Group
  - US Healthcare Information Technology Standards Panel (HITSP) will interact in a local, regional and national health information network for the United States

- Increasing engagement among different actors
  - In 2006, Siemens Medical Solutions and the Technical University of Munich were piloting a system that builds on the concept of interoperability by transferring clinical data gathered at the point of care for use in clinical trials
  - EFPIA EHR Task Force
  - US HITSP/CDISC
  - Consortia like IMI (Innovative Medicines Initiative).
A Changing Environment in EU & US New Opportunities...(III)

- Adoption of EHRs is on a steady incline

In the US (2007):

- 11% of community hospitals had fully implemented EHR systems
- 57% have partially implemented
- 32% have not yet started
- EMR use in physician practices is estimated at 20%.

# Expected Impact of EHR Integration on Drug Development

## Prioritized High-Level Use Cases

<table>
<thead>
<tr>
<th>Clinical Research</th>
<th>Clinical Development</th>
<th>Regulatory &amp; Safety</th>
<th>Commercial</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>c. Investigator Services</td>
<td>c. P-Epi &amp; Data Mining</td>
<td>15. e-Prescribing</td>
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<tr>
<td></td>
<td>d. Compliance</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>e. Placebo Populations</td>
<td></td>
<td></td>
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<tr>
<td>4. Clinical Trial Simulation</td>
<td>11. Manufacturer’s Recall</td>
<td></td>
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<tr>
<td>5. New Indication Identification</td>
<td>12. Pharmaco-economics</td>
<td></td>
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<tr>
<td>6. Interim analyses</td>
<td></td>
<td>13. Marketing Comparative Studies</td>
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<td></td>
<td>8. Outcomes Studies</td>
<td>15. e-Prescribing</td>
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<tr>
<td></td>
<td>9. Disease and Care Management Modeling</td>
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</tr>
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Reference: Slipstream project
Electronic Health Records

*Expectations of 35 Pfizer senior executives* (1)

(1) DAIJIN KIM et al
“Opportunities for Electronic Health Record Data to Support Business Functions in the Pharmaceutical Industry—A Case Study from Pfizer, Inc.”
Electronic Health Records

*Expected Qualitative Benefits include…*

- ‘Pre-flight’ feasibility of protocols
- Auto (?) identification of suitable patients for trial
- Enhanced investigation site selection
- Reduced duplication of data entry at site leading to a removal of transcription errors for a significant proportion of the trial data
- Decreased/changed Source Data Verification needs
- Earlier access to trial data at entry into EHR
- No need to produce archive DVDs at the end of the trial as data moved electronically back to the patient record
- No need to deploy hardware to site.
## Electronic Health Records

### Potential Quantitative Benefits (Illustrative) (*)

<table>
<thead>
<tr>
<th>Trial Design (Refining Inclusion / Exclusion Criteria)</th>
<th>Patient &amp; Investigator Recruitment (Patient Recruitment)</th>
<th>Execution Analysis (Patient Compliance Tracking)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• EHR alerts increased enrollment rates from 2.4% to 22% of recruited patients (Prior knowledge of health status could drive further improvement)</td>
<td>• Studies show EHR data can drive:</td>
<td>• Journaling compliance increased from 11% with paper-based methods to 94% electronically</td>
</tr>
<tr>
<td>• Total cost savings for screening 40,000 patients with a 5% “hit” rate is approximately $3.2 million</td>
<td>• A 28% increase in eligible patient identification</td>
<td>• EHR-based monitoring enables intervention before patient must be excluded from datas et</td>
</tr>
<tr>
<td></td>
<td>• A doubling of monthly patient enrollment rate</td>
<td>• Use of EHR data and patient alerts reduces attrition rate by 50%, reducing overall trial size</td>
</tr>
<tr>
<td></td>
<td>• A near ten-fold increase in the enrolled to referred ratio</td>
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### Potential Savings: $3.2 Million

### Potential Revenue Estimate: $125 Million

### Potential Savings: $1.8 Million

**Assumptions for Calculating Savings & Additional Revenue**

- Phase III clinical trial
- 40,000 patients screened given 5% “hit rate”
- 2,000 patients enrolled in anticipation of 25% attrition rate
- Recruitment expected to last 250 days
- Per patient screening cost: $100
- Cost per enrolled patient: $6,000
- Anticipated product revenue: $1 M/day

(*) Secondary uses of Electronic Health Record (EHR) data in Life Sciences. ©2009 Deloitte Development LLC
Electronic Health Records

Just One Use Case …

• The Mayo Clinic used EHR for rapid prospective recruitment of patients with heart failure (HF). The use of coding systems in HF patients is challenging due to syndromic nature of the disease which cannot be confirmed with a single diagnostic test.

  Goal: The use of EHR for patient identification has to be validated on a case-by-case basis. The study therefore validated 2 approaches for prospective recruitment of HF patients. One approach uses NLP (natural language processing), the other uses predictive modeling.

Results:

  – Both approaches enable accurate and timely case identification provided patient medical records become available electronically (at Mayo Clinic, within 24 hrs)
  – NLP might be more suitable for studies requiring the highest sensitivity such as observational studies
  – Predictive modeling due to its higher positive predictive value appears the better screening mechanism for clinical trials.

(1) Pakhomov, Serguei et al.
Electronic Health Records

Challenges – some examples

- EHR penetration varies greatly across countries
- Completeness of electronic patient data sets at Healthcare site as well as those needed for pharmaceutical drug development is limited
- Only clinical data processed through regulated and validated systems (GxP, PART 11 etc compliant) can be submitted to Heath Authorities for market access
- Patient data coding in Health Care and Drug Development follows different standards
- Point to point ‘EHR Site to Pharma Sponsor’ pilot projects demonstrating the ability to leverage EHR data for clinical research are limited in business value, as these projects typically concern a particular region, therapeutic area, and/or local stakeholders and unlikely to be scalable.
Convergence across Pharma and Healthcare

**Barriers to Interoperability**

(Percent of respondents/Number of respondents)

- Legal and ethical factors: 32% (8)
- Changing the IT system: 28% (7)
- Time/costs/qualified resources: 28% (7)
- Maintaining patient confidentiality: 28% (7)
- Setting up an efficient business model and getting leadership commitment: 28% (7)
- Putting in place common data standards: 24% (6)
- Linking the different databases: 20% (5)
- Competition: 20% (5)
- Identifying the strategy for change (government): 16% (4)
- Building relationships/trust: 16% (4)
- Lack of understanding of importance of interoperability: 12% (3)
- Issues over who owns the data and intellectual property: 12% (3)
- Time to put in place changes: 8% (2)

Note: Sum of all percentages exceeds 100 percent because respondents gave multiple answers. n = 27.

Source: IBM Institute for Business Value.

(2006) – based upon interviews with Astra Zeneca and Karolinska’s Institute & Hospital
Electronic Health Records

Domains of Challenge – New Opportunities

- **Legal and regulatory** (data privacy, GCP,..)
  - If not done: Risk of too complex/restrictive regulatory framework

- **Organization & process** (third party, targeted drug development with PHC)
  - If not done: Not affordable to have full integration
  - Limited impact compared to current situation

- **Technology & data standards**
  - (specific services around patient recruitment, safety, protocol feasibility.. Including core data sets and standards)
  - If not done: Still a lot of manual mapping.... And no re-use of clinical care data

Courtesy of Innovative Medicines Initiative (IMI)
Electronic Health Records

Challenges – Need for New Organizational Model

Current Organization

Each pharmaceutical company connected with different hospitals

⇒ many links per organization

Trusted Third Party

Each actor connected through a Trusted Third party (e.g. SWIFT in banking - )

⇒ one link per organization (Note: in Health Care we would rather foresee a federation of natl. TTPs)

Many to many interactions are not sustainable

⇒ New organizational/interaction models are needed

⇒ The “desired” model may be between the extremes displayed above
Vision 2015
EFPIA EHR Task Force

• Access to EHR’s will drive
  – improved patient outcomes and
  – provide the foundations required for targeted medicines and Personalized Health Care (PHC)

• The use of EHRs will transform Drug Development and Commercialization, provided
  – broadest access to interoperable records is available
  – there is a collaborative effort between stakeholders including Health Care and Pharmaceutical industry.

For Patients, Providers, Payers and Pharma: a Win-Win-Win-Win-Win scenario
Electronic Health Records
What Pharma has to offer…

- Subject matter expertise and knowledge in a broad range of functional areas, including but not limited to:
  - Clinical trial design and trial execution
  - Clinical data management, data analysis and statistics
  - Data standards and data coding
  - IT including systems testing and validation
  - Knowledge Management
  - Safety, Epidemiology and Health outcomes research
  - Business analysis, Strategic planning and Business planning
  - Legal including country specific local regulations
  - Ethics policy, Data privacy and Intellectual property policies
  - Financial control and audit capability
  - Project management.
Electronic Health Records

Conclusions

• There is an increased understanding in industry, at EU level and in academic research about the need to collaborate in order to create synergies in the field of re-use of EHR data for medical research

• EHR integration for supporting medical research
  – is opening new possibilities from academic research to drug development
  – is a complex undertaking with organizational, legal and technical implications

• Pharma appears committed
  – In increasing their proximity to Healthcare and patients and to promote the importance of clinical research as a special case for the secondary use of healthcare data
  – In knowledge acquisition and competency development on EHR
  – To an integrated healthcare environment that benefit Patients, Healthcare Academic Research and Biopharma.
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Contact
• Andreas Schmidt, F. Hoffmann-La Roche AG - Pharma Development, Grenzacherstrasse 124, CH–4070 Basel, Switzerland. Mail: andreas.schmidt.as3@roche.com

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