



# EHR4CR ENABLING PROACTIVE RESEARCH

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# Why change how I currently operate?

- To more visible to the clinical trial community (and, in the future, patients)
- To accelerate patient recruitment processes
- To streamline processes, stop redundant data entry
- To derive greater value from EHR data



A manual process misses **27%** of suitable candidates compared with electronic searching<sup>1</sup>



**50%** of today's clinical trials fail to achieve the target recruitment rate<sup>2</sup>



The percentage of studies that complete enrolment on time: **18%** in Europe, **7%** in the US<sup>3</sup>



Investigational sites estimate that over **70%** of data are duplicated between EHR and clinical trial systems<sup>4</sup>



Each day a drug is delayed from market, sponsors lose up to **\$8m<sup>5</sup>**

1. CSC Use of Real Life Data for Clinical Research and Personalised Medicine – Webinar; November 2012.
2. Tufts <http://clinicalperformancepartners.com/wp-content/uploads/2012/07/Fixing-Feasibility-Final-Jan-2012.pdf> 2012
3. State of the Clinical Trials Industry: A Sourcebook of Charts and Statistics, Center Watch, 2008
4. EDC Site Survey: Investigational Site Perspectives on Clinical Trial Information Systems, eClinical Forum 2009. Available at: [www.eclinicalforum.org](http://www.eclinicalforum.org) (accessed December 1, 2011)
5. Beasley, "Recruiting" 2008

# The burden of running a clinical trial has increased

- Protocol design
  - Trials have become increasingly complicated
  - More endpoints to observe as science has expanded knowledge about how to measure safety and effectiveness
- Patient recruitment
  - Larger on average and require more participants. Recruitment has become more difficult and expensive
- Data capture and exchange
  - More data collected, more routine...
  - ... more work

THE GROWING COMPLEXITY OF CLINICAL TRIALS

	1999	2005	% Change
Unique Procedures per Trial (median)	24	35	46%
Total Procedures per Trial (median)	96	158	65%
<b>Clinical trial Staff Work Burden</b> (measures in work-effort units)	21	35	<b>67%</b>
Length of Clinical Trial (days)	460	780	70%
Clinical Trial Participant Enrolment Rate	75%	59%	-21%
Clinical Trial Participant Retention Rate	69%	48%	-30%

Source: PhRMA Report 2010



# The clinical trial journey today is fragmented with many hurdles

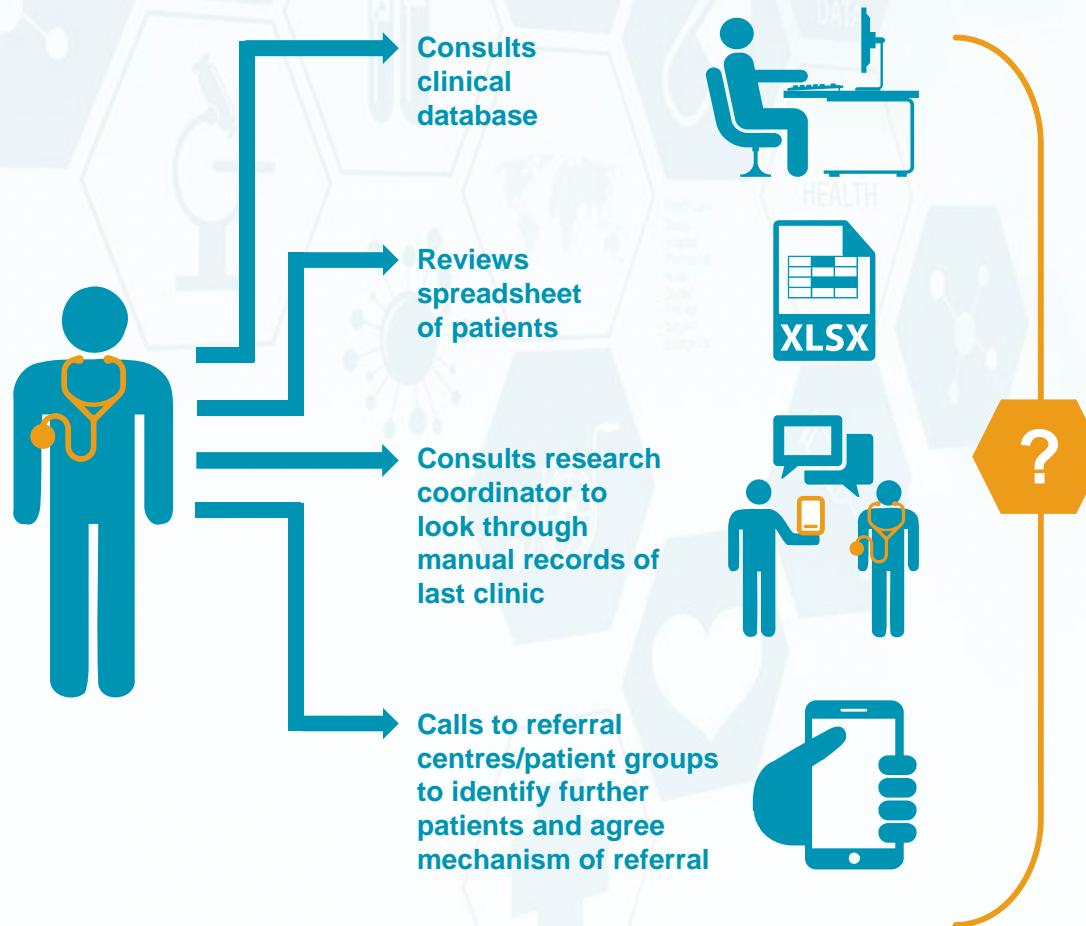


# Detailed Feasibility – hospital perspective

If your hospital is approached to take part in a clinical trial...

An investigator completes questionnaire or meets team to assess interest and potential pool of eligible patients

More robust patient numbers, recruitment plan and operational capability then assessed



Based on these estimates, this trial has a **50%** chance of achieving the target recruitment rate

- Patient number agreed
- Payment agreed
- Contract drawn up

# Identifying an eligible patient – an example

Hospital database - EHR



Multidisciplinary team sees patient & classifies tumour

Patient record



Written and filed

Clinical researcher



Manually identifies patients against inclusion/exclusion criteria

Investigator validates information and consents patient during first visit

Clinician may note down this patient as one that could be suitable in study they recall

Clinician may remember to alert investigator or research nurse about a potential patient that was reviewed at this clinic...



# Access to health records speeds up protocol design and patient recruitment

PATIENTS PROTECTED BY LEGAL AND PRIVACY PROTECTION STANDARDS & REGULATIONS

EHR becomes patient data repository to streamline clinical trials



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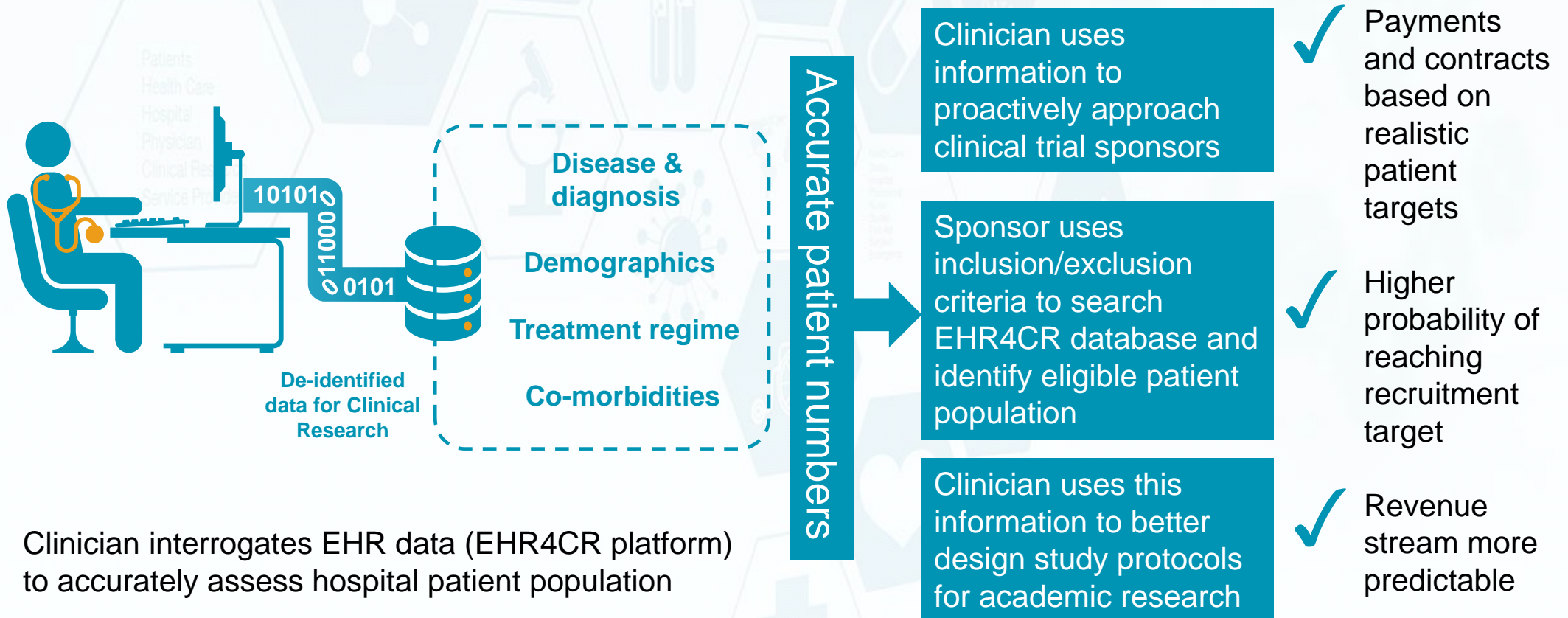
## ▪ Evaluate patient populations in study set up

- Query EHR database to establish number of potential candidates
- Improve and validate study designs

## ▪ Accelerate patient identification and recruitment

- Query EHR database to select sites and identify and recruit patients
- Implement study screening parameters into patient registration and scheduling
- Researchers obtain key health information before patients arrive for a screening visit (after consent)

# A streamlined process for protocol feasibility...



Clinician interrogates EHR data (EHR4CR platform) to accurately assess hospital patient population

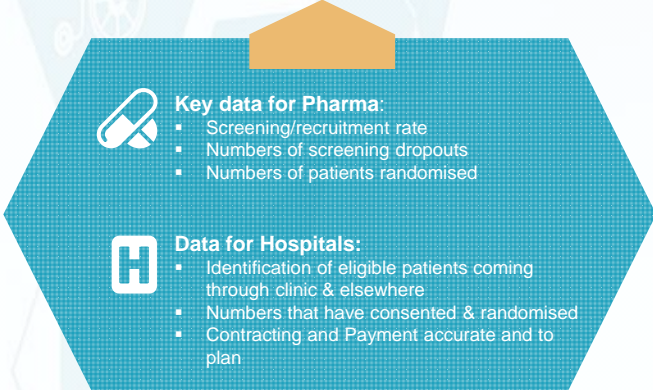
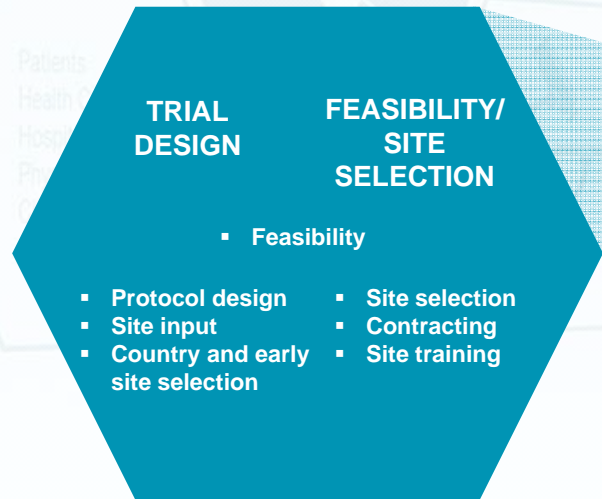
1. Drug Information Journal, Vol 45, 2011
2. Industry Standard Research, 2010



Electronic Health Records for Clinical Research



# ...could result in a much simpler clinical trial journey



# Proactive partnership in conducting clinical research

- With research and healthcare systems sitting on the same spine and conforming to the same data exchange standards, the re-use of EHR information is possible on a large and scalable way – across:
  - organisations
  - regions and
  - countries



# Creating value for hospitals



Patients  
Health Care  
Hospital  
Physician  
Clinical Research  
Service Providers



**Improved clinical research**  
Improved efficiencies and interconnectivity with other hospitals facilitates, streamlines and enriches clinical research



**Enhanced reputation**  
Greater visibility of hospital/clinicians in scientific community. Improved ability to participate in/conduct clinical trials



**Income stream**  
Better placed to generate income from clinical research. At a time of squeezed budgets, income from research can help drive innovation and efficiency with better outcomes for patients



**Better quality EHR data**  
Improved monitoring, performance benchmarking, reporting and management (e.g. reimbursement coding) Drives optimisation of patient care and improved efficiencies