

## ROUNDTABLE ON REGISTRIES

Practical Considerations for Registries – making them work



26 January 2017, Pullman London St Pancras, London, UK

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## ROUNDTABLE ON REGISTRIES

Practical Considerations for Registries – making them work



Registry: how to set up spontaneous reporting – practical challenges, information sharing, multi-source environment, limitation of registry data

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# Registry: how to set up spontaneous reporting – practical challenges, information sharing, multi-source environment, limitation of registry data

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Clinical Lead Adult IBD service  
Clinical Lead UK IBD registry

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# What is the purpose of a registry?

“An organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves a predetermined scientific, clinical, or policy purpose(s)”

Gliklich et al 2010

# Inputs: Obtaining data

- Identify and enroll representative patients
- Collect data from multiple sources and settings
- Use uniform data elements and definitions
- Link data from different sources
- Maintain security and access

Gliklich et al 2010

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# Outputs: Care delivery and coordination

- Provide real time feed back (with decision support?)
- Generate patient level reports and reminders
- Send relevant notifications to providers and patients (supported self management, monitoring etc)
- Share information with patients, other providers
- Link to relevant patient education Gliklich et al 2010

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# Outputs: population measurement and QI

- Provide population level reports
  - Standardised measures
  - Benchmarking
  - Different reports for different levels of user
- Enable ad-hoc reports
- Provide utilities to manage populations or subgroups
- Generate dashboards
- Facilitate 3<sup>rd</sup> party quality reporting Gliklich et al 2010



## **IBD Registry**

Making  
**information work**  
for **patients,**  
their **clinical teams**  
and the **NHS**



# IBD Registry Purpose

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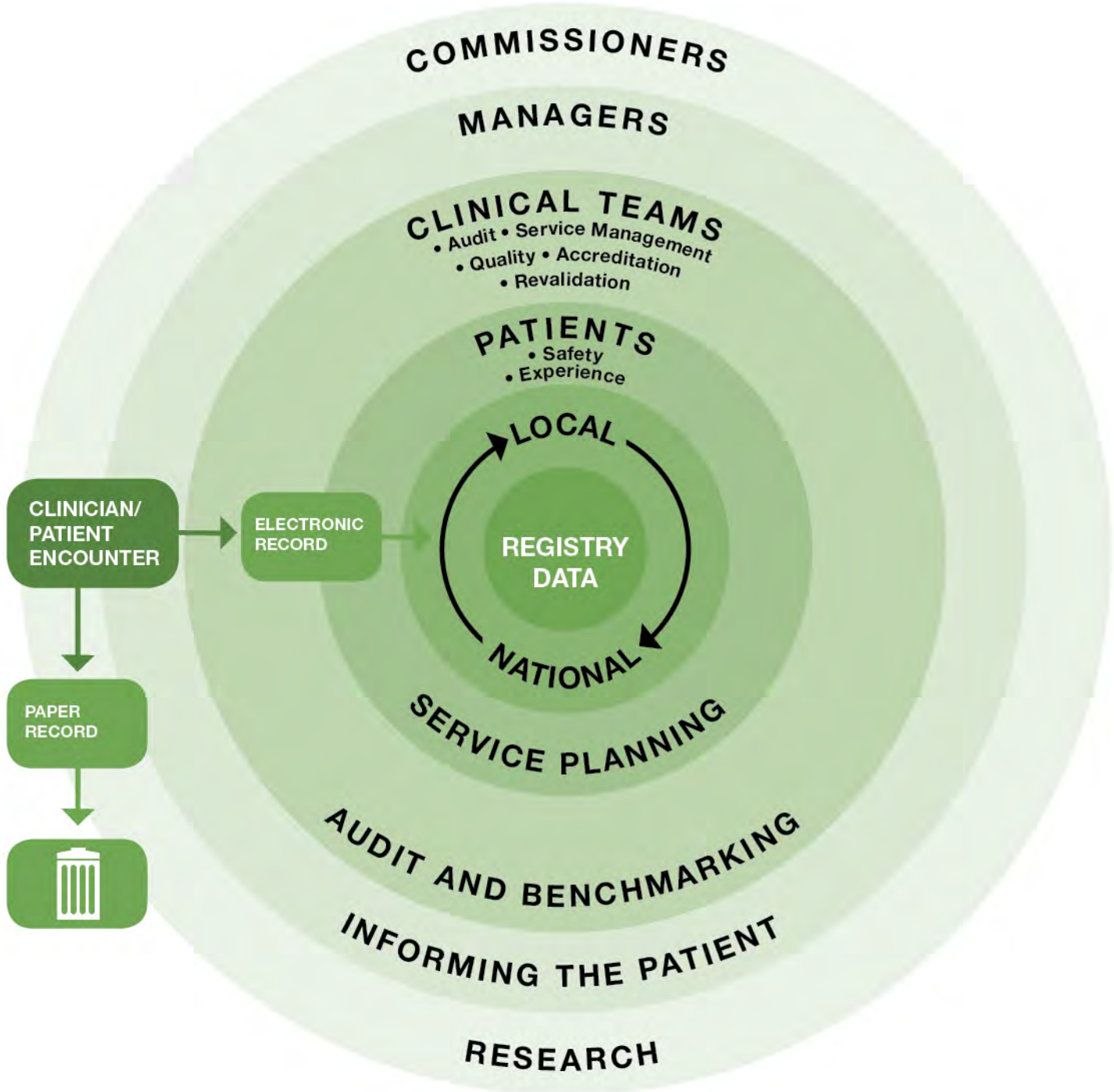
The IBD Registry will provide the first ever UK-wide repository of pseudonymised IBD adult and paediatric patient data for prospective quality assurance, audit and research purposes. Bringing this data together for the first time will:

- Drive continuous improvement in patient care and access to care across the UK
- Inform commissioning and service design
- Improve our understanding of long term outcomes
- Provide local, regional & national data in order to better define the pattern of ulcerative colitis and Crohn's disease
- Support IBD research

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Enter data once and use for  
multiple purposes





# Data entry options

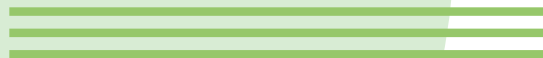


## IBD Registry

UK IBD Registry

A Central Anonymised Dataset of IBD Patients

- Reports
- Outputs
- Analysis
- Feedback
- Data for Research
- Quality Measures
- Performance



WEB TOOL

**e.g. Rotherham,  
EMIS etc**

**(discounted) costs  
payable to supplier**

**currently free of  
charge**

# Data Submission Framework

- Standardised data definitions
    - Demographics
    - Phenotype
    - Medications
    - Disease activity scores
    - PROM
  - Data extract structure to facilitate upload to NHS Digital via secure portal
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# Data Collection tools

- Duplication of data entry
- Supplier engagement
- Technology?
- NHS IT
  - Resources
  - Engagement

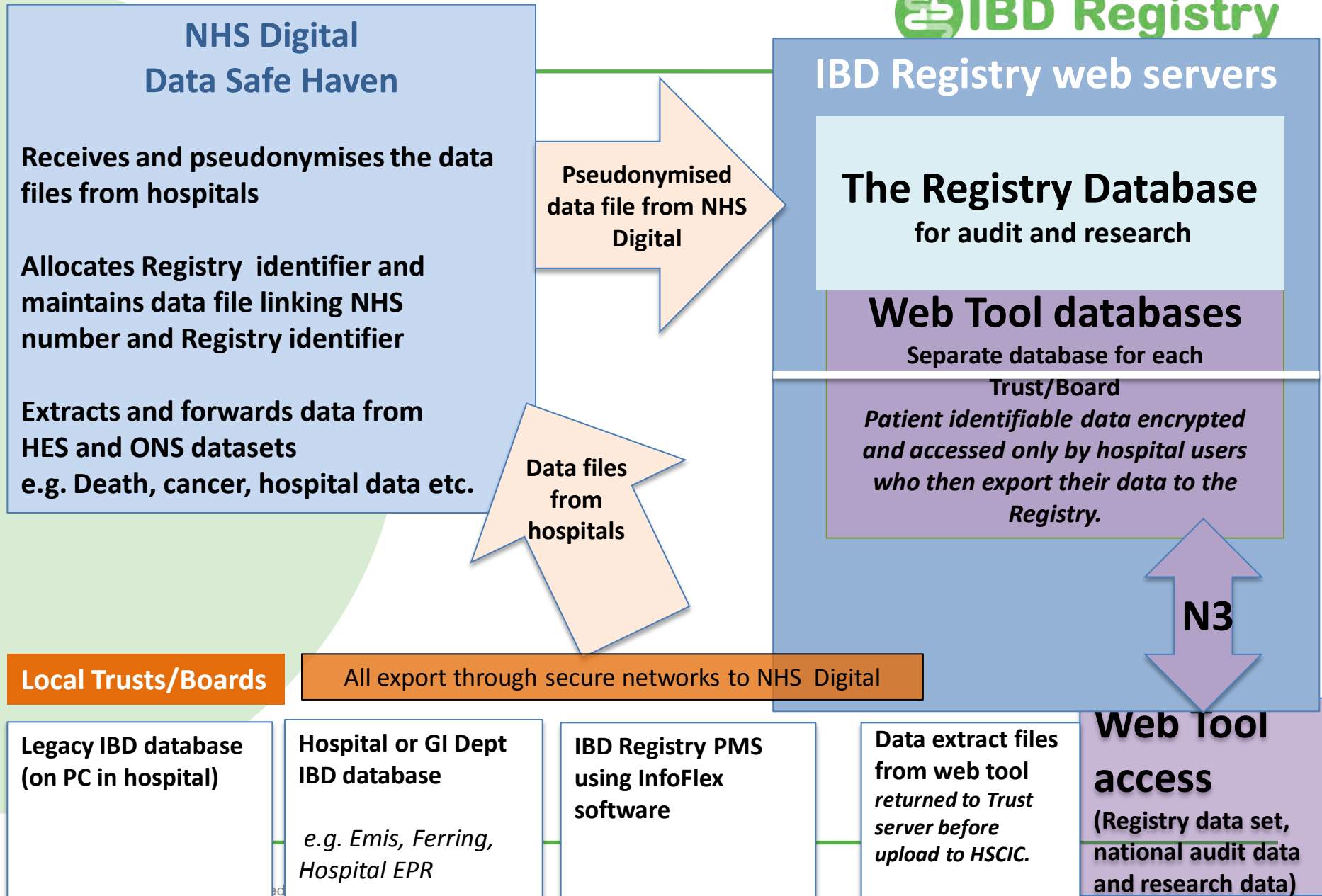
# Using the tools: behavior change?

- Cultural change
- Time
- Technology adoption
- IT system challenges
- Incentives?
- NHS support



- Patient Summary
  - MDT
  - Flare line
  - Nursing support
  - Drugs
    - Biologics
    - IMM monitoring
    - Steroids
    - 5-ASA
  - Cancer Surveillance system
  - Bones
  - Letters
    - GP
    - Patient Summary, information etc.
  - Virtual clinics
-

# Overview of Registry data-flow & pseudonymisation in England



# Data governance.....

**NHS** NHS patient data to be made available for sale to drug and insurance firms

Privacy experts warn there will be no way for public to work out who has their medical records or how they are using it

Randeep Ramesh, social affairs editor

Sunday 19 January 2014 21:34 GMT

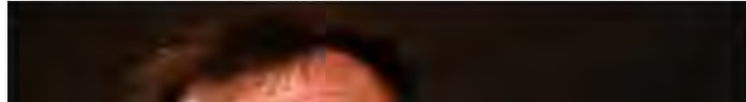


**NHS** NHS data will not be sold to insurance companies, Jeremy Hunt says

Health secretary to provide assurance that confidential information will not be used for commercial insurance

Press Association

Friday 28 February 2014 23:31 GMT



HOME » NEWS » HEALTH » HEALTH NEWS

## Nearly 1million patients could be having confidential data shared against their wishes

Calls for an official investigation as it is disclosed that at least 700,000 patients opted out to having their GP data shared with third parties only to have their demands ignored.

By Peter Dominiczak, Political Editor

6:34PM BST 05 Jun 2015

# The Telegraph

# Why Pseudonymise? NHS Digital?

- Identification of patients for future research
- HES data linkage
- Linkage to other NHS England databases

BUT

Huge bureaucratic challenge

# IBD Registry

Information for Patients

THIS HOSPITAL IS TAKING PART IN THE UK IBD REGISTRY

The IBD Registry collects information about patients who have Inflammatory Bowel Disease (IBD) to:

- Help hospitals improve their service
- Improve our understanding of how IBD affects people
- Support research into IBD

What does it mean for me as a patient?

Some information about your IBD will be sent to the IBD Registry. A system has been put in place to protect your confidentiality and you can read about this in the IBD Registry Information Leaflet.

The information collected will help to improve patient care, but if you do not want your information to be used then it is your right to opt out. Please speak to your IBD doctor or nurse if

you have any questions or you want to opt out. Opting out will not affect your treatment in any way.

Please ask a member of staff for an information leaflet or you can obtain one from our website at [www.ibdregistry.org.uk](http://www.ibdregistry.org.uk)

IBD Registry  
British Society of Gastroenterology  
3 St Andrews Place, Regent's Park  
London NW1 4LB  
Tel: 020 7935 3150  
Email: [info@ibdregistry.org.uk](mailto:info@ibdregistry.org.uk)  
Website: [www.ibdregistry.org.uk](http://www.ibdregistry.org.uk)

The British Society of Gastroenterology is registered in England. Charity number 11449074

WHICH ORGANISATIONS ARE INVOLVED IN THE IBD

## IBD Registry

### IBD REGISTRY CONSENT FORM

The purpose of the IBD Registry is to collect information about Inflammatory Bowel Disease (IBD) across the UK.

Collecting this information will:

- Help hospitals to improve their care of people with colitis and Crohn's disease
- Improve our understanding of how people's lives are affected by IBD
- Help the NHS to design better services
- Support research into IBD

Please read the IBD Registry Information Leaflet and then initial the boxes below to confirm how you wish your personal information to be managed:

1(a) I give permission for relevant information from my health records to be submitted to the IBD Registry for analysis and audit.	<input type="checkbox"/>
OR	
1(b) I do not wish information from my health records to be submitted to the IBD Registry.	<input type="checkbox"/>
If you have agreed to information being submitted to the IBD Registry, please also consider the following three options and initial the boxes if you agree:	
2 I give permission for the information held and maintained by the Health and Social Care Information Centre and other central UK NHS bodies to be used to provide information to the IBD Registry about my health status.	<input type="checkbox"/>
3 I give permission for information from my health records to be submitted to the IBD Registry and used for studies run by approved external researchers.	<input type="checkbox"/>
4 I give permission for the information held by the Health and Social Care Information Centre to be used to contact me in the event of a research project for which I might be suitable.	<input type="checkbox"/>

Patient's name \_\_\_\_\_

Patient's signature \_\_\_\_\_ Date \_\_\_\_\_

Staff member's name and role \_\_\_\_\_

Staff member's signature \_\_\_\_\_ Date \_\_\_\_\_

For further information about the IBD Registry, please look at the project website at [www.ibdregistry.org.uk](http://www.ibdregistry.org.uk)  
The IBD Registry is managed by the British Society of Gastroenterology which is a charity registered in England & Wales. Charity number 11449074

IBD Registry Consent Form for adults - England & Wales - January 2015

# IBD Registry - Information for Patients

The IBD Registry is a national project to collect information about Inflammatory Bowel Disease (IBD) from across the UK for the first time.

Collecting this information will:

- Help hospitals to improve their care of people who have colitis or Crohn's disease
- Improve our understanding of how people's lives are affected by IBD

be contacted.

How is the confidentiality of my personal information protected?

Relevant information about you, your medical record and your IBD care is sent by your hospital to the Health and Social Care Information Centre (HSCIC). Before the HSCIC sends that information to the IBD Registry, they change your identifiable personal information into a different format so that no one at the IBD Registry can identify any individual patient. (This process is called pseudonymisation.) The HSCIC keeps a master file so that future information can be added to the right patient's registry record and hospitals can be told if any of their patients are suitable for a clinical research study.

What is the Health and Social Care Information Centre (HSCIC)?

HSCIC is an organisation which is approved for their standards of data security and confidentiality, and which is authorised to collect and process information about patients and the healthcare they receive. The information the HSCIC holds, including information available to them from other central UK NHS bodies, may be used for analysis of the healthcare you receive, to help contact patients (e.g. about a research project for which they might be suitable) or to provide information to the IBD Registry about patients' health status.

What identifiable personal information will be used?

Your NHS number, postcode, date of

Which organisations are involved in the IBD Registry?

The IBD Registry is run by the British Society of Gastroenterology, supported by:

- Crohn's and Colitis UK
- CICRA - Crohn's in Childhood

- Association of Coloproctology of Great Britain and Northern Ireland

- British Diabetic Association

- British Society of Gastroenterology

- British Society for Paediatric Gastroenterology, Hepatology and Nutrition

- Primary Care Society for Gastroenterology

- Royal College of Nursing - Gastrointestinal Nursing Forum

- Royal College of Physicians - IBD Programme



# Consent

- Currently s251 exemption
  - Linkage of registry data to NHS records
  - Their information to be used for
    - non-commercial research projects
    - Commercial partners (report only)
      - Research
      - Pharmacovigilance
  - Contacted for future research projects
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# Who should fund registries?

- NHS?
- Specialist Societies?
- Industry?
- Individual NHS trusts?
- Charities?
- Research funders?

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# Collaboration/opportunities

- UK IBD Biologics audit
  - UK Quality Improvement Program
  - Academic
    - Crohn's and Colitis UK/Dr Keith Bodger
  - Industry
    - Pharmacovigilance projects
    - Real world evidence
    - Specific projects
      - VEST
  - Anaemia service evaluation
-



# The story so far....

- Infrastructure and governance
- 23,000 patients
- 40 sites actively up loading data
- 80 set up to up load data
- 150 expressions of interest to participate in audit

# Aims for 2017

- Focus on biologics treated patients
  - Funding model
    - Subscription model
    - Pharma projects/support
  - Reporting
  - Data visualisation
  - Pharmacovigilance system
-

# Conclusions

- Huge opportunity to change patient care
- Culture change
- Registry infrastructure
- IT platforms
- Funding
- Defined outputs