

The UK National Haemophilia Database: a thumbnail sketch!

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And the UK NHD.



NHD: Administrative Inter-Relationships and Funding.

The UK National Haemophilia Database.

- Established in Oxford in 1968 at the request of the Dept. of Health.
 - Moved to Manchester 2002.
- All Haemophilia Centres in the UK are required (and recently contracted) to report to NHD on all patients with bleeding disorders.
- Data collection supported by a network of data managers and haemophilia specialist nurses.
- Named Database.
 - Patient permission.
 - DPA compliant.

National Haemophilia Database

Accountable:

=
Data
Management
WP.
UKHCDO.
UKHCDO Ltd
Board.
Commissioners
Haemophilia
centres
Caldicott
Guardian.
Information
Commissioner.

Support:-

Staff.
MDSAS.
City View
House

Outsourced support

Peninsula
(personnel)
Porters
(accountancy
and payroll)
Staff Insurers
UKHCDO
Board.
Centres

Service: -

Data for: -
Commissioners
DoH.
UKHCDO WPs
Research
Haem. Soc.
WFH
Industry
(EMEA etc)

Funding of the Database

- Commissioners.
 - Annual SLA with NHS England, DH Scotland and the Welsh Office.
 - N. Ireland are non-participants.
- DoH and other Govt. Projects.
 - National Procurement and contract monitoring.
 - HCV Lookback etc.
 - The Penrose Inquiry.
- Industry projects and unrestricted grants.
 - Inhibitor surveillance.
 - Data to support regulatory applications.
 - Novo Post-marketing Study.
 - Others ongoing.
- Grants from other grant giving bodies

NHD: IT Structure and Strategy.

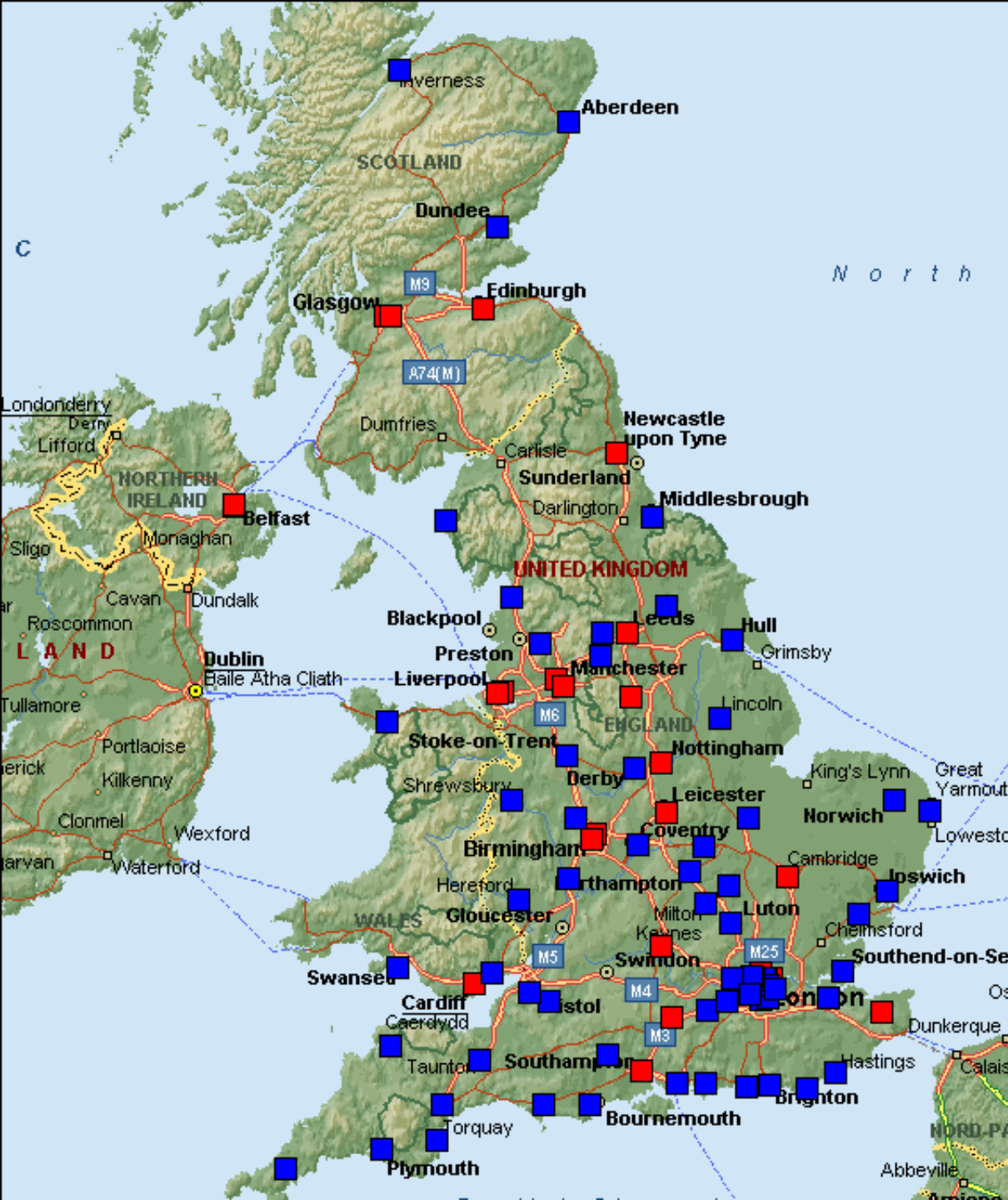
UK Network: All Haemophilia Centres in the UK networked to the NHD.

-  Haemophilia Centre
-  Comprehensive Care Centre

25,000 + bleeders
Haemophilia A 6500
Haemophilia B 1200
25000 bleeders.

NHD

U.K.H.C.D.O NATIONAL HAEMOPHILIA DATABASE



National UK Haemophilia IT Systems

A fully integrated software system



Patient Home Treatment System



HCIS

Haemophilia Clinical Information System

DATA FLOW



UK Haemophilia Information Service



National Haemophilia Database

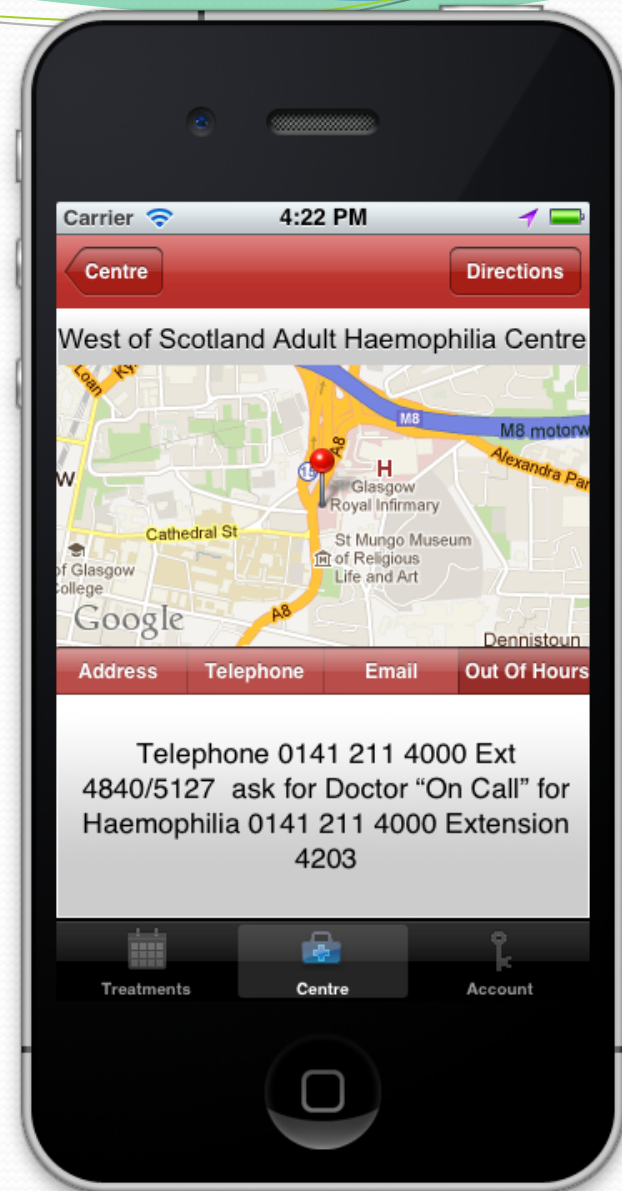




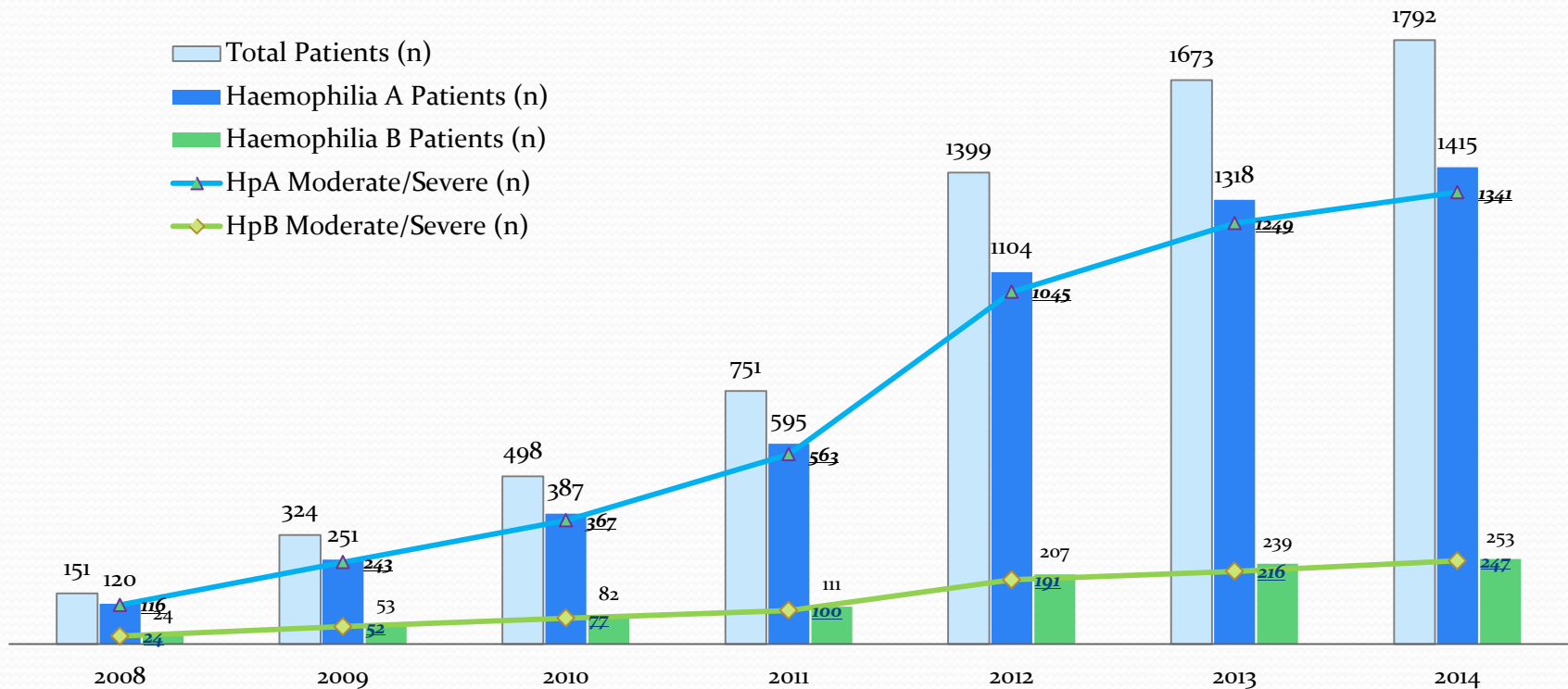
- Patient-reported home-treatment system.
- Android and I-phone apps and PC and paper.
 - Used for any bleeder on home therapy.
 - Mainly haemophilia A and B but also VWD, factor XIII etc.
 - Report all treatments: -
 - Dose/brand/batch.
 - Reason for treatment (prophylaxis/bleed/follow up/ITI etc)
 - Bleed details
 - Cause, position/type, dose interval, pain score, effect on normal activity.
- *System strongly endorsed by the Commissioners.*
 - Who wish all home-therapy pts to use the system.

Haemtrack Developments: –

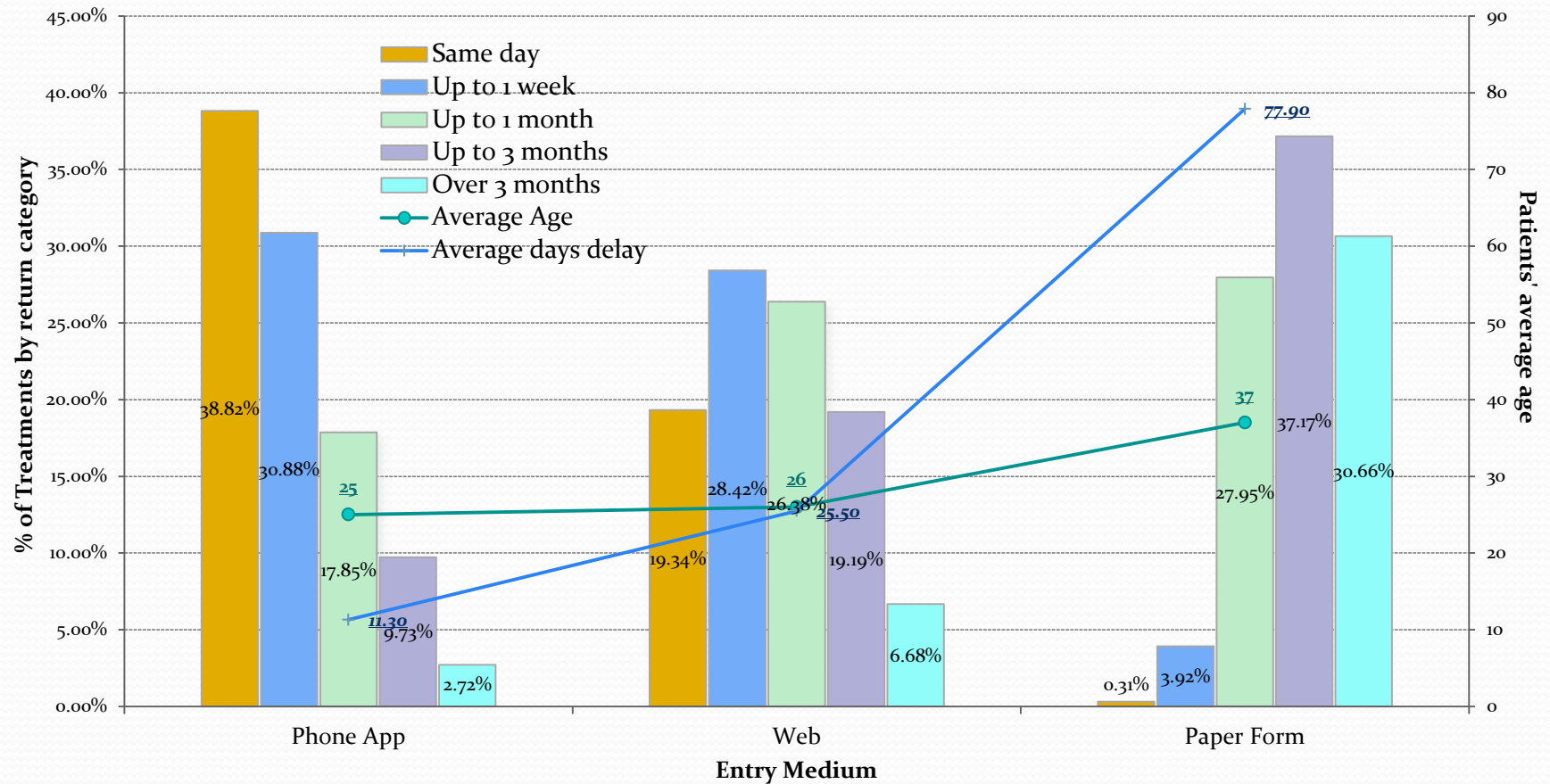
- Bar-code reading
- Stock-control.
- Linked with home-delivery provider
- Video-consultation.
- QOL and other research instruments



Number and Diagnosis of Pts using Haemtrack 2008-14



Haemtrack Reporting Delay by Reporting Medium 2014



Haemtrack Diary View


HOME THERAPY SUPPORT SERVICE

[Home](#)
[Add Treatment](#)
[Add Multiple Treatments](#)
[Admin](#)
[Help](#)

Welcome Joe MDSAS Bloggs ! [Logout](#)

My Guide

The calendar to the right provides you with an at-a-glance view of your treatment entries for a month.

To begin adding a new treatment entry, simply click the date of the treatment on the calendar.

To view/edit/delete a treatment entry select the entry from the calendar.

Android Sync

You last synched on
24 October 2014 at 10:04

Key

- New Bleed
- Follow-up Bleed
- Prophylaxis
- Centre Event
- NEW** New Treatment (Added Today)

Help

[<< Previous](#)
October
2014
[Next >>](#)

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
29	30	1 11:45 AM 2000 IU	2	3 NEW 11:00 AM 2000 IU	4	5 NEW 10:00 AM 2000 IU
6	7 NEW 11:00 AM 2000 IU	8	9 NEW 9:00 AM 2000 IU	10	11 NEW 11:00 AM 2000 IU	12
13 NEW 9:00 AM 2000 IU	14	15	16	17	18 NEW 2:00 PM 2000 IU	19 NEW 9:00 AM 2000 IU
20 NEW 10:00 AM 2000 IU	21 NEW 11:00 AM 2000 IU	22	23	24	25	26
27	28	29	30	31	1	2
3	4	5	6	7	8	9

[Add Multiple Treatments](#)

HaemTrack Test Centre

Contact Info	Opening Times
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NHD: What Data do we collect?

Cradle to the Grave Data Collection: Severe Haemophilia A.

- All patients: -
 - All personal identifiers, DoB,
 - Diagnosis and genotype.
 - Bodyweight, F. History, and ethnicity.
 - Individual treatment statistics. (Quarterly).
 - Haemtrack treatment/bleed-level data as it comes in.
 - Adverse events and morbidity.
 - Outcome.
 - Mortality Data.
- Prospective inhibitor risk-factor data from birth to death
- Full list on WWW.ukhcdo.org

Centrally Reported Outcome Measures:

Current: -

- Annualised bleed rate (Haemtrack).
- Annualised joint score.
- Factor consumption and regimen used Treatment-level data through Haemtrack.
- Pharmaco-vigilance
 - Inhibitors/ thrombosis/reactions etc.
- Death (age/cause)

Future: -

- QOL measures.
- Loss of time from school/work
- PK

Adverse Events Reported:

- Factor VIII Inhibitors
 - Poor Efficacy event.
 - Other possible adverse or unusual event.
 - Allergic or other acute events.
 - Transfusion transmitted infection.
 - Thrombosis
 - Malignancy
 - Intracranial haemorrhage
 - Death
- *Events are reported electronically direct to NHD as they occur and shared with EUHASS.*

UKHCDO Inhibitor Dataset

We are attempting to collect this information on all patients with severe Haemophilia A, so that we have the denominator for these events.

Definitions: -

Severe <0.01 IU
PTP >50 ED

Surgery/peak Rx Moments:

Units used.
Details of event.
Continuous infusion / Bolus

Data collected quarterly: -

Date of any brand change.
Individual factor usage IU/kg.
EDs

And for inhibitor Pts.

Titre. Diagnostic and peak.
Method.
EDs
ITI data/outcome

New inhibitors are reported as they arise.

Full list on WWW.UKHCDO.org

We are trying to address the generic questions.

- Natural History of Haemophilia:
 - Incidence, life expectancy and causes of death.
 - Treatment statistics and trends for healthcare planning.
 - **Outcome and treatment-level data to inform future treatment and treatment trends.**
- Pharmacovigilance:
 - Is the treatment safe?
 - What and how frequent are side-effects
- What are the host and environmental risk-factors for inhibitors.

Data Quality!



Haemtrack Data Quality Strategy:-

- Patient education:-
 - Leaflet and training from centre.
 - Standardisation of definitions.
 - Regular review of data in clinic with pt. and by phone/e-mail.
 - Sanctions for non-compliance.
- Centre Education;
 - Leaflet/training sessions/ publications/reports.
 - Optimal use of system.
 - Data validated *at centre level* before central upload.
- Central data reconciliation.
 - With centre product issues.
 - Feedback errors to centres

Data Quality

- Regular HCIS training (3-4 times a Year)
 - Open to ANYONE.
- Educational leaflets on Haemtrack for Pts and Centres.
- Data cross-checks and constant data cleaning.
 - E.G. Cross check overall centre reported usage with sales and Pt reported usage with issues etc.
 - We attempt to triangulate the data.
- Automated data reconciliation.
- We intend to employ CRAs to do centre-level data monitoring

Database achievements:

- Influences treatment practice and health policy.
- National Procurement.
- Annual and quarterly reports.
- Regular publication in peer reviewed journals
- Collaboration with CRN.
- Collaboration with Industry/Regulators: -
 - Supportive data for regulators e.g:-
 - Benefix <6 yrs data. Benefix once weekly prophylaxis
 - ReFacto-AF PUP study (>100 UK Pups).
 - Novo post –marketing study for EMA (270 ug/Kg dose)
 - Market modelling data: Sobi, Bayer.

The Pros and Cons of post-licensure Database Data for Industry and Regulators:

Clinical Trial:

- GCP/FDA Standard.
- Good quality data.
- Recruitment difficult.
- Selected patients,
- Small sample size.
- Short follow-up
- Very expensive to conduct.
- Analysed by industry.
- Potential industry bias.

National Database:

- Not GCP/FDA standard
- Lower quality data.
- Recruitment very easy.
- Unselected pts.
- Large sample size.
- Long follow up
- Relatively inexpensive.
- Independently collected and analysed.
- Real world data.

The background is a solid blue color. At the top, there are several thin, wavy lines in shades of blue and green, creating a decorative header effect.

**Thank you for your
attention.**

NHD Inter-Relationships

