

# National, centralised hospital datasets can inform clinical trial outcomes in prostate cancer: a pilot study in the STAMPEDE trial

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**WIN conference 24/01/17**

University of Warwick



# Aim

- **Develop a method to identify major clinical trial events in prostate cancer**
- **Testing if clustering of routinely collected NHS data correlates with these major clinical events**

The background of the slide is a grayscale micrograph of biological tissue, likely showing various cellular structures and possibly a developing embryo or a specific tissue section. The image is semi-transparent, allowing the text to be clearly visible. A central black rectangular box contains the text 'Research stage 1' in a bright blue, sans-serif font.

# Research stage 1

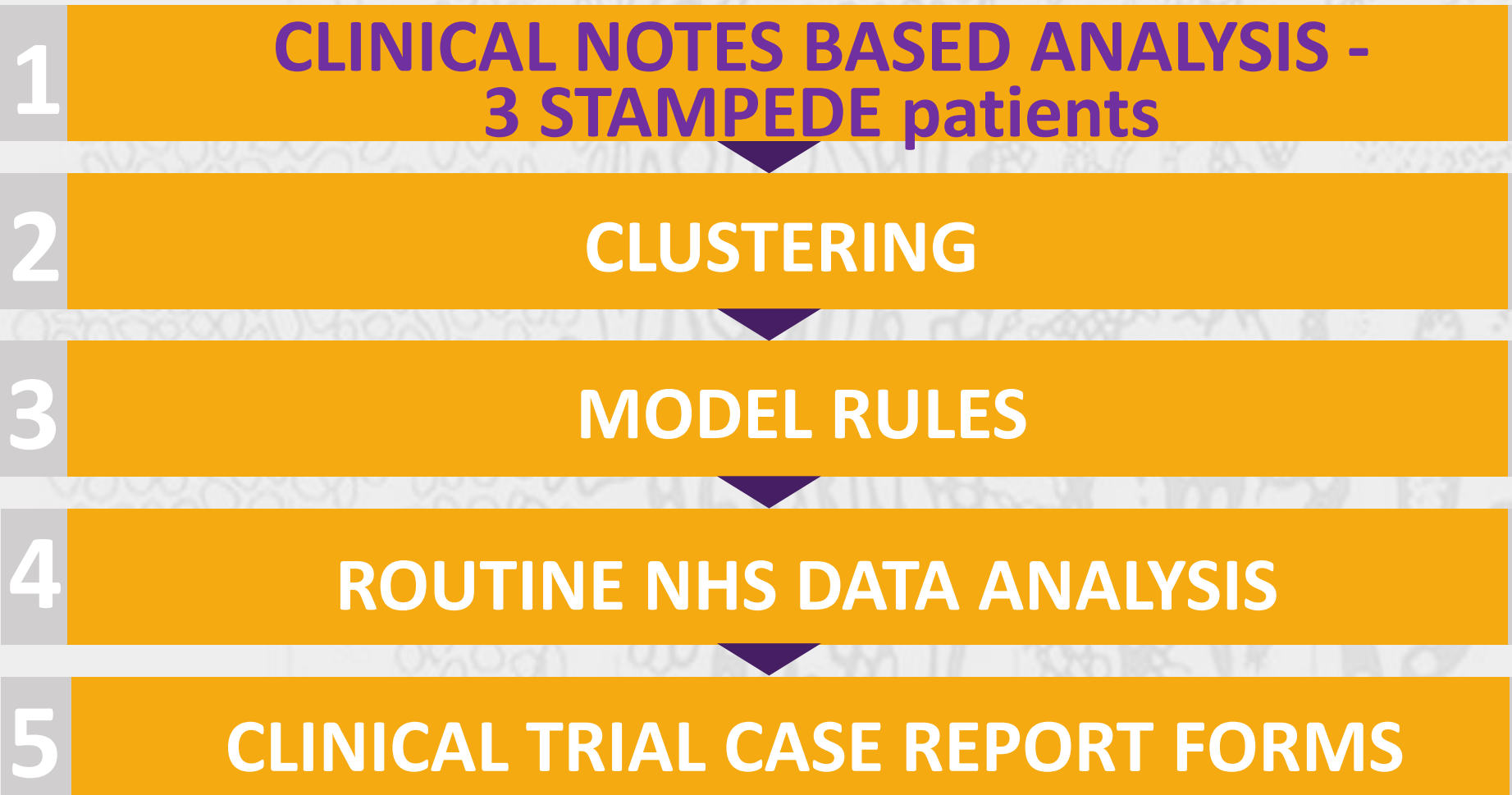
# Data sources

- **Hospital clinical records**
- **NHS England Hospital Episode Statistics (HES)**
- **Clinical trial Case Report Forms (CRFs)**

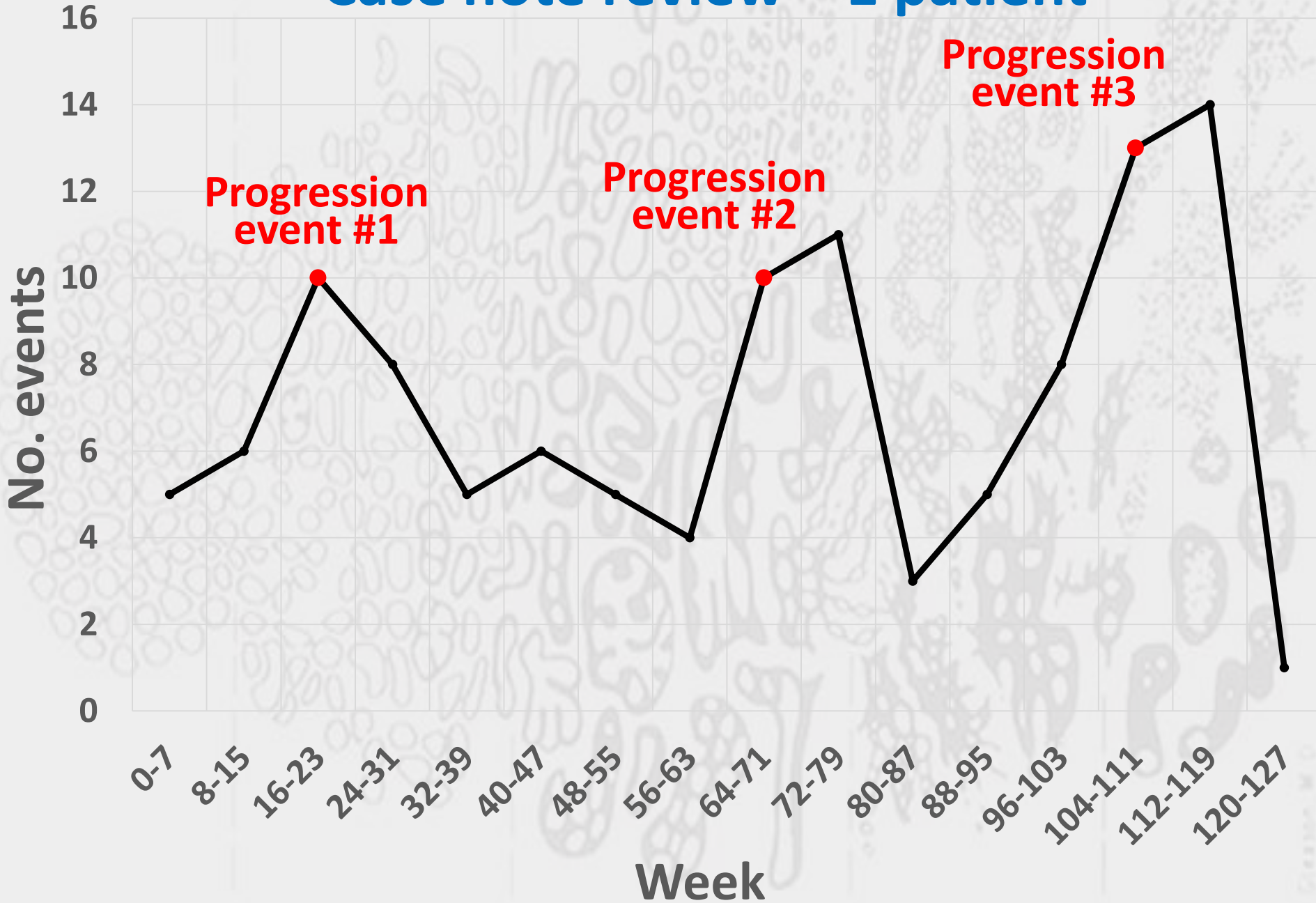
# Patients

- **STAMPEDE patients**
- **Queen Elizabeth Hospital Birmingham**
- **Patients stage 1 analysis: 5**

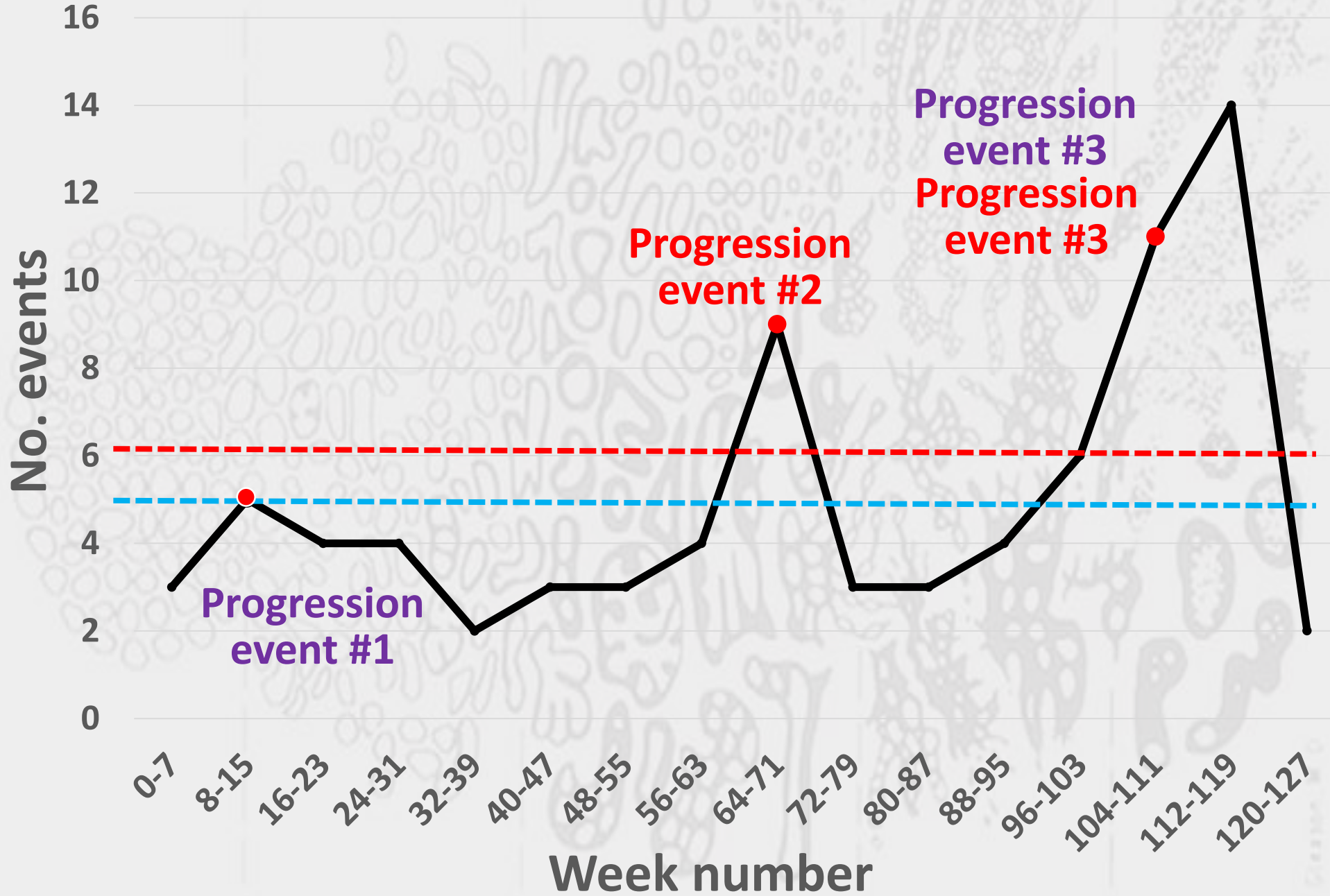
# Method



# Case note review – 1 patient



# Routine data analysis





# Method cont.

6

**ROUTINE DATA ANALYSIS –  
2 STAMPEDE patients**

7

**MODEL VERIFICATION**

8

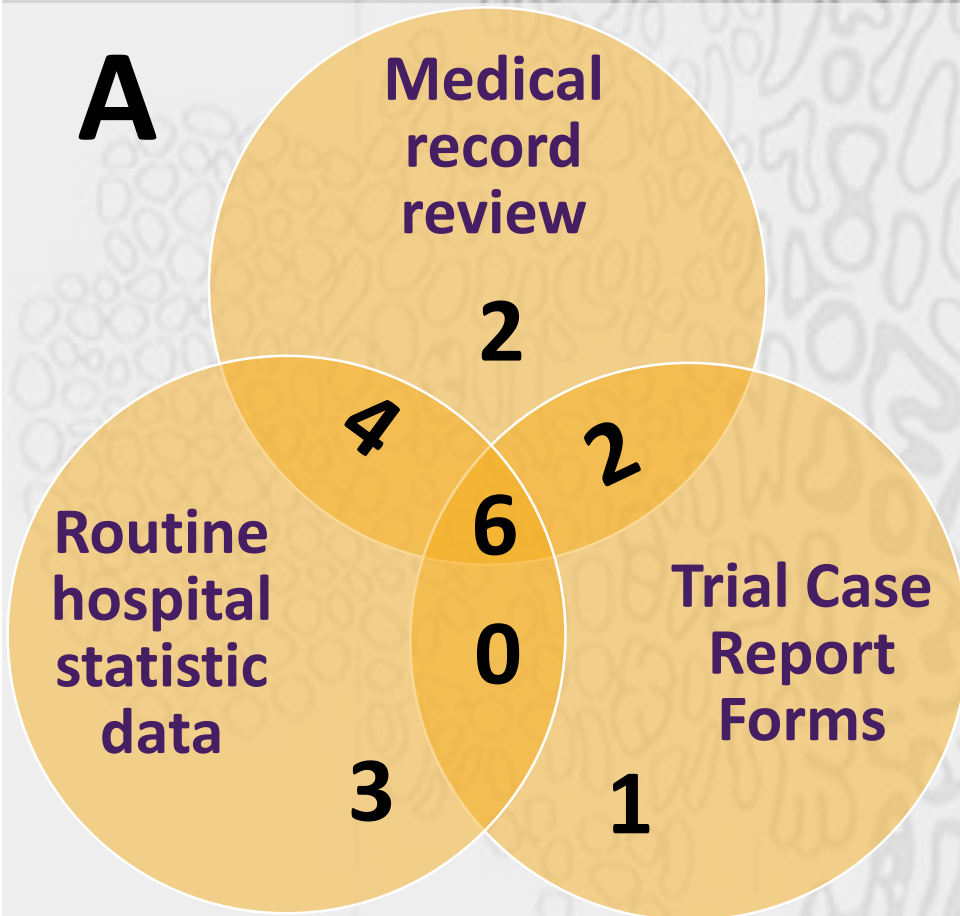
**MODEL REFINEMENT**

9

**CONFIRMED ROUTINE DATA ACCURACY**

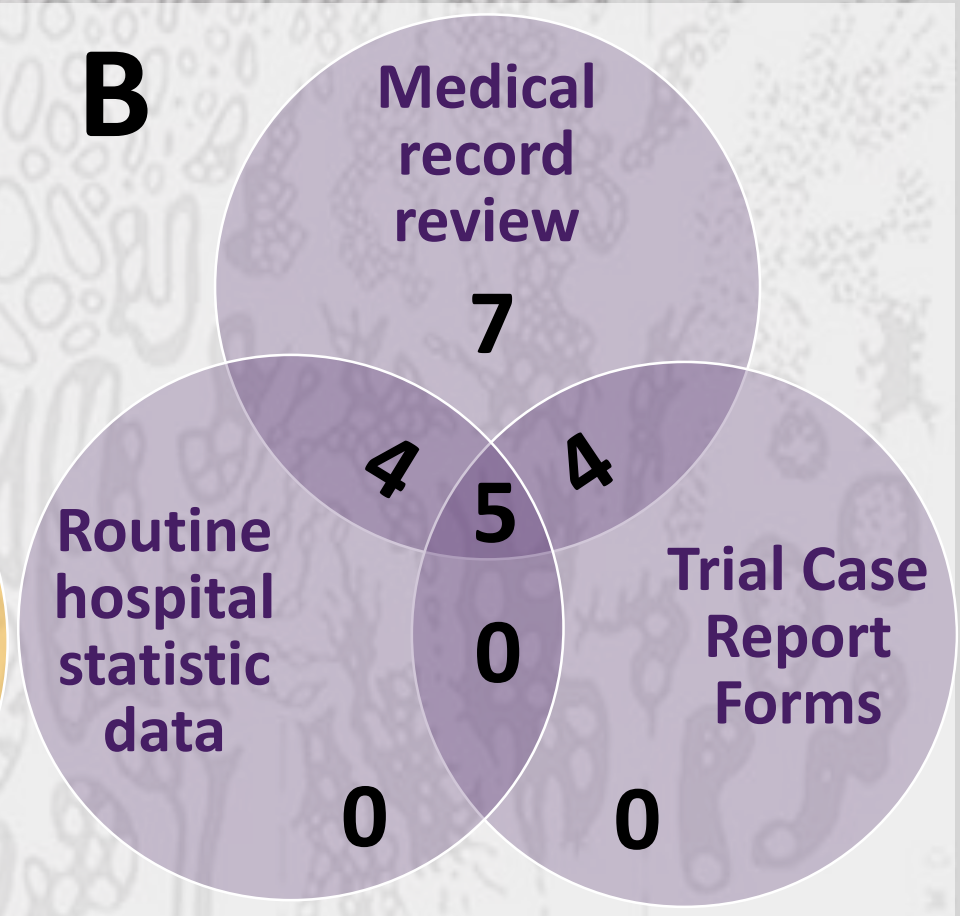
# Results

**A**

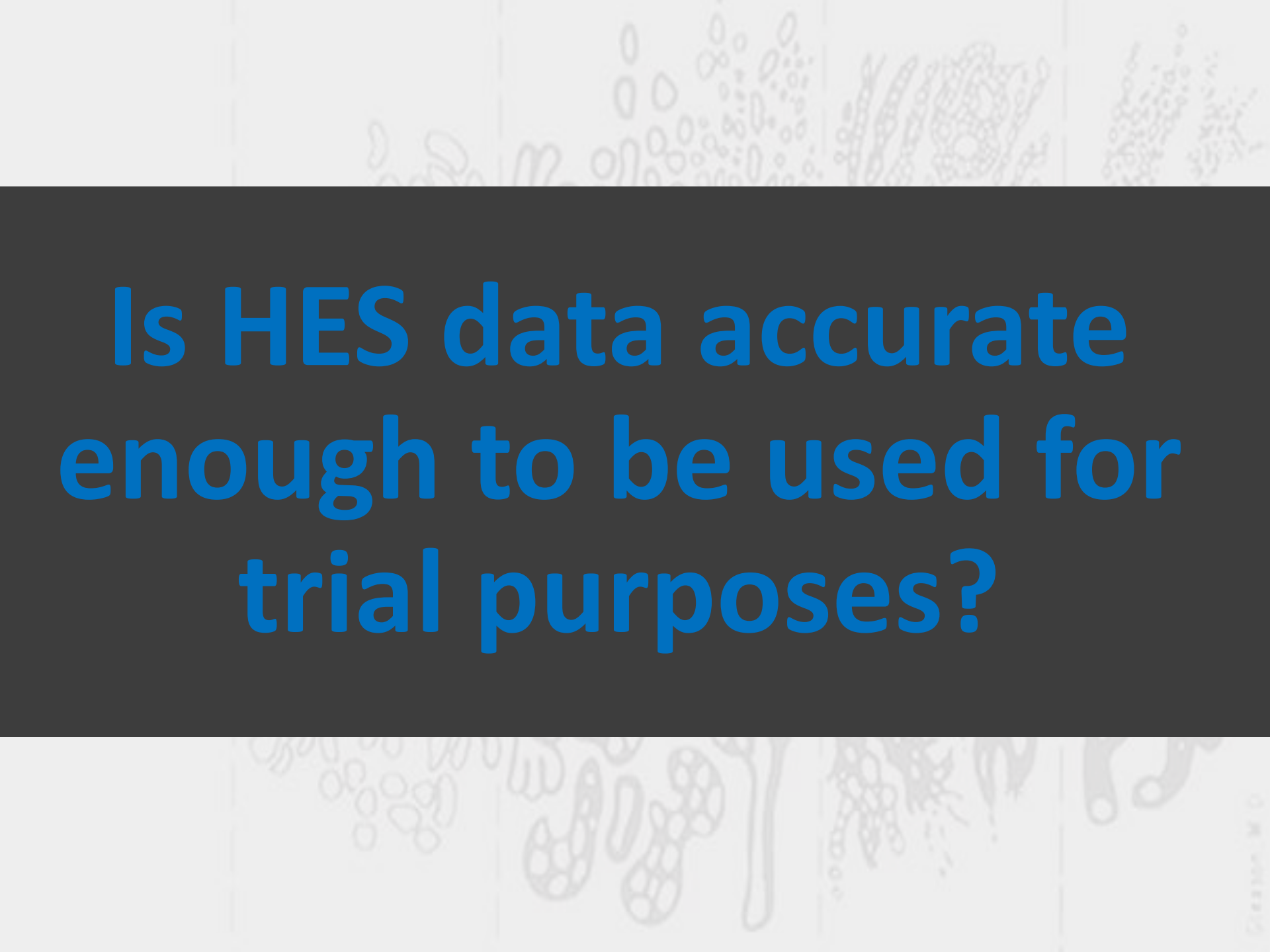


**Progressive Disease Events**

**B**



**Skeletal Related Events**

The background of the slide features a light gray, semi-transparent pattern of various microscopic organisms, including what appear to be bacteria, fungi, and possibly larger eukaryotic cells, arranged in a grid-like fashion. The central text is overlaid on a dark gray horizontal band.

**Is HES data accurate  
enough to be used for  
trial purposes?**

# Accuracy

Data	Number events	% accuracy
Total confirmed events	199	REFERENCE
Routine hospital statistics	149	75
Medical record review	191	96

**Routine data was 75% accurate**

# Overall results cont.

Events coincided with routine data clustering

Routine hospital statistics data found:

- 71% of progressive events (10/14)
- 4 extra events that trial data missed
- missed 4 events (but further model refinement using SRE coding identified 2 of these)
- 4 SREs not found in trial data

The background of the slide is a grayscale, semi-transparent image of a histological section, likely showing glandular or epithelial tissue. The image is divided into vertical columns by faint dashed lines. A prominent feature on the left is a large, rounded cluster of small, uniform cells. To the right, there are several elongated, tubular structures, some containing internal cellular details. The overall appearance is that of a detailed biological illustration or a high-magnification micrograph.

# Research stage 2

# Stage 2 (in progress)

- 1) **Algorithm creation**
- 2) **Algorithm validation: 50 STAMPEDE patients**
- 3) **Analysis: Compare events from routine data output to trial data**

**Stage 3: Further validation on >150 patients**

**Stage 4: Validation: all England patients**

# Summary

## Algorithmic analysis of routine data:

- identified **more** events than traditional trial data
- identified the **majority** of events compared to note review
- **aided** the collection of Skeletal Related Event data

**With suitable testing HES can be used for primary clinical trial data**



# References

1. HSCIC. Hospital Episode Statistics- <http://content.digital.nhs.uk/hes> (accessed 28 October 2016)
2. James ND. The Protocol, Systemic Therapy in Advancing or Metastatic Prostate Cancer: Evaluation of Drug Efficacy (A multi-arm multi-stage randomised controlled trial). v15 29/03/16  
[http://www.stampededtrial.org/87548/87552/STAMPEDE\\_Protocol\\_v15.0\\_clean.pdf](http://www.stampededtrial.org/87548/87552/STAMPEDE_Protocol_v15.0_clean.pdf)
3. Grieve R, Abrams K, Claxton K, Goldacre B, James N, Nicholl J, Parmar M, Parker C, Sekhon JS, Smeeth L, Spiegelhalter D. Cancer Drugs Fund requires further reform. *BMJ* 2016;354:i5090
4. Thorn, J.C., Turner, E., Hounsome, L., Walsh, E., Donovan, J.L., Verne, J., Neal, D.E., Hamdy, F.C., Martin, R.M. and Noble, S.M., 2016. Validation of the Hospital Episode Statistics Outpatient Dataset in England. *Pharmacoeconomics*, 34(2), pp.161-168.