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Managing Change and Conflict During a CRO Insolvency

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RB is a growing franchise in consumer health with almost 200 years of history

1823

Benckiser founded a chemical business in Germany



1840

Isaac Reckitt rented a starch mill and manufactured starch to found Reckitt



1930s

Optrex eye care launches. Joins RB in 2006



1943

Air Wick launches in USA

1948

Disprin – 1st soluble Asprin launches



1951

Senokot laxative launches. Joins RB in 1960



1965

Gaviscon launches. Joins RB in 1970



1969

Lemsip launches



1978

Buprenorphine as Temgesic launches – fore runner to Suboxone

2010

Durex & Scholl join RB



2013

Collaboration agreement with BMS in LatAm (Tempra, Luftal)

2016

Hypermarcas



2017

RB divests Food Business



2017

RB Acquires MJN



January 2018

RB creates two Business Units
Health
+
Hygiene Home

1888

Reckitt & Sons launched on the London Stock Exchange

1912

Lehn & Fink Products begins US production of Lysol



1932

Harpic Lavatory Cleaners bought. Medically-endorsed Dettol launched



1950s

Finish launches into the automatic dishwashing market



1958

Strepsils medicated sore throat lozenges launches. Joins RB in 2006



1983

Nurofen launches. In 2006 it joins RB



2002

Mucinex trade marked; becomes OTC in 2004 & joins RB in 2008



2012

Schiff including MegaRed joins RB

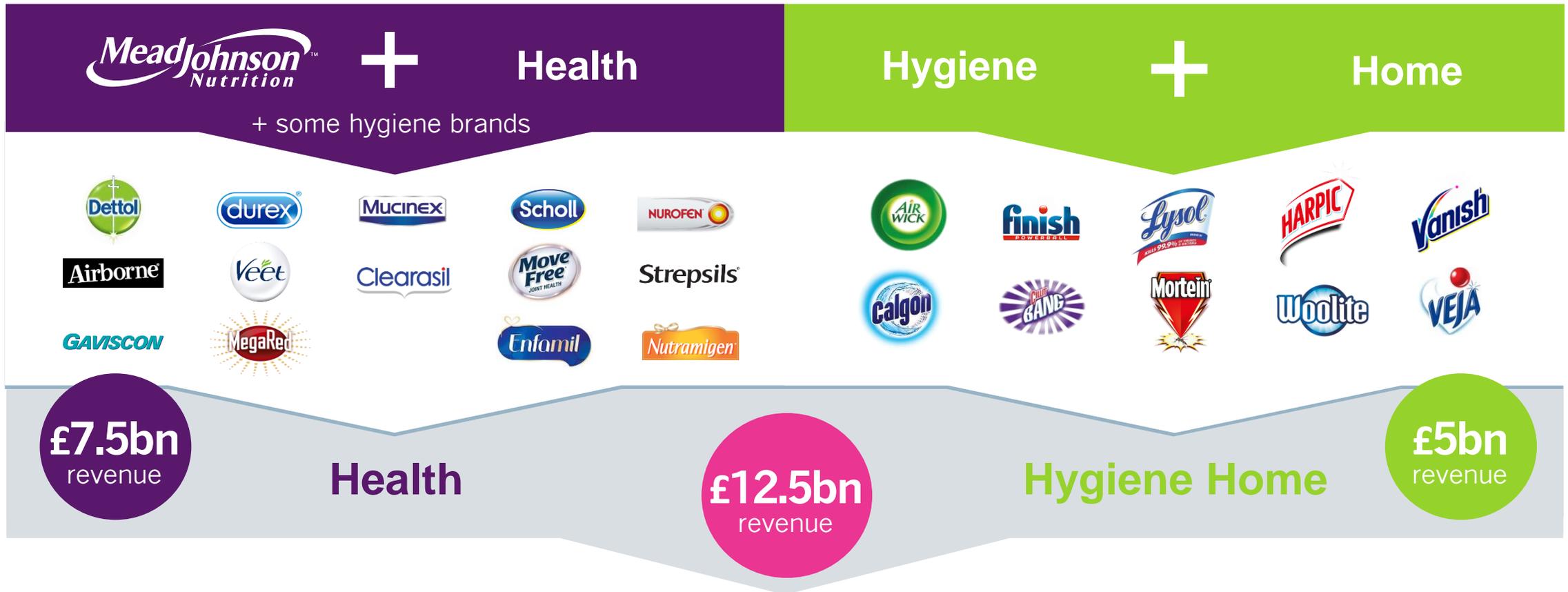


2014

KY joined RB



The RB business is structured to enable category focus and leadership



One RB

A platform for long term growth and outperformance

Product classifications and study types



Medicines

4 main types of study:

1. **Human Pharmacology**
(e.g. Bioequivalence)
2. **Therapeutic Exploratory**
(e.g. Pilot study)
3. **Therapeutic Confirmatory**
(e.g. Pivotal registration study)
4. **Therapeutic Use**
(e.g. PASS)



Medical Devices

Clinical Investigation Plans are undertaken in human subjects to assess:

- **Safety** and/or
- **Clinical Performance**

And evaluate whether the device is **suitable for the purpose(s)** and the population(s) for which it is intended



Cosmetics & General Products

Safety studies, e.g.:

- Skin irritation – Acute Tolerance
- Product efficacy

Claims studies:

- Relevant for both marketing and product



Non-Interventional

- **Real world evidence** and big data, e.g. using 3rd party database on pain indications to support new claims
- **Outcomes & value research**, e.g. Outcome measures (patient) & payer / economic analysis
- **Healthcare Professional** – medical insights



Outsourcing, Budgeting, Forecasting



Data Analytics, Biostatistics & Data Management



Quality Management System: Fit-for-Purpose SOPs



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Study background

- Pivotal efficacy study – Multi-centre, multi-country, phase III, double-blind, placebo controlled study for an OTC drug
- At the time - Largest study of its type conducted in Europe by RB and an unprecedented investment
- Conducted in two European countries with established clinical research track record and standards (country A & B)
- 256 patients to complete - 19 sites split across the two countries – GPs and SMO
- Outsourced full-service, including site contracting. RB oversight of CRO



Study set-up

- The contracted CRO were based in country B and did not have a presence in country A
- Local partner CRO sub-contracted for services in country A
- CRO responsible for identification, set-up and management of all sites
- Sites were contracted directly with RB in country A and with the CRO in country B, in accordance with site standards
- IMP management was provided by RB, via a separate IMP vendor, under RB's contract and management



Study progress

- Study set-up completed and FSFV was achieved 28th April 2015
- ‘Standard’ study challenges encountered – No major issues
- RB-CRO governance in place to build relationship and mitigate issues and conflicts – Trust established
- Some recruitment challenges were faced during Q3 2015 – Advertising was deployed to overcome this, approved Q4 2015



What happened next...

Immediately prior to implementation of advertising, RB received notification from the CRO that they were going into Preliminary Insolvency

A dark, irregular ink blot with splatters on a white background. The blot is roughly circular but has jagged, uneven edges, suggesting it was made with a brush or a thick marker. The color is a deep, dark brown or black. There are several smaller, lighter brown splatters around the main blot, particularly towards the top and right sides. The overall effect is one of a messy, accidental mark.

Now what??!

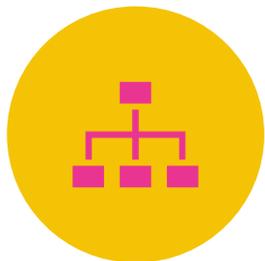
There were many challenges and conflicts



Assessing risk



Site payments and relationships



Subcontracted local CRO



CRO – Contract termination and appointment of a rescue



Assessing Risk

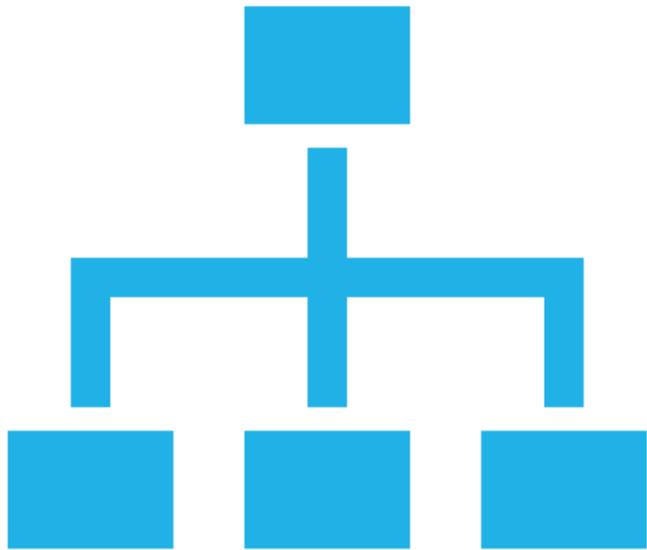
- Internal
- Cross-functional
- Patient safety
- Data integrity
- Recruitment
- Budget status
- Situation changed **hourly**, as information came to light
- Differing opinions = Conflict
- Stakeholder management was key



Site payments and relationships

- Significant monies owed – Disgruntled PIs
- Lack of communication from CRO – RB intervention
- Legal conflict – Country B insolvency laws prevented direct payment to sites
- All monies paid by RB were in escrow, to be distributed by the Administrator; No RB or CRO control
- Administrator conflict – Lack of cooperation; Impact on sites

Subcontracted local CRO

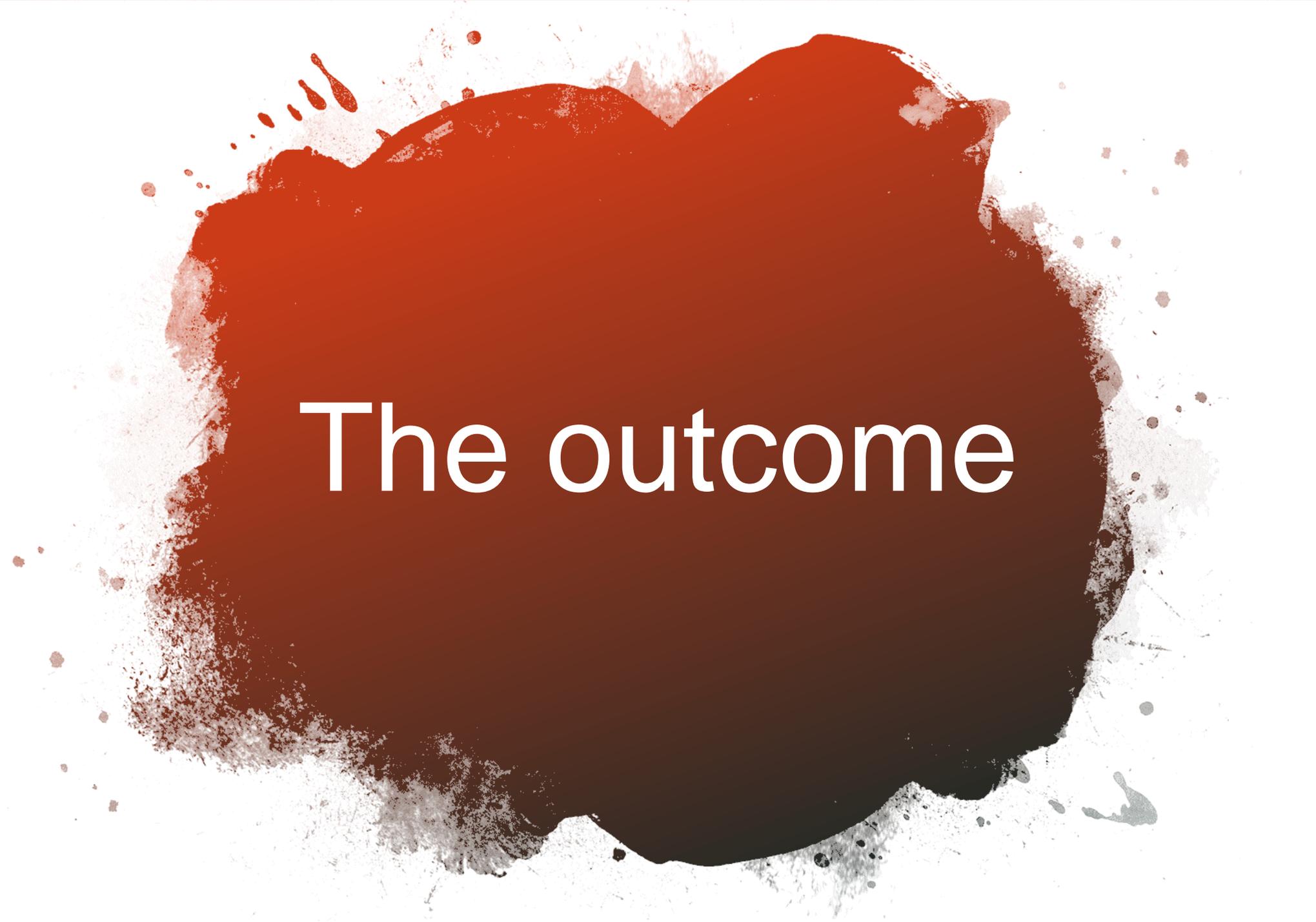


- Significant monies owed – Angry CEO
- Country B insolvency laws prevented payment by RB
- Conflict with CEO
- Verbal contract assumed
- Legal intervention to calm situation
- Conflict with Administrator required resolution prior to release of monies



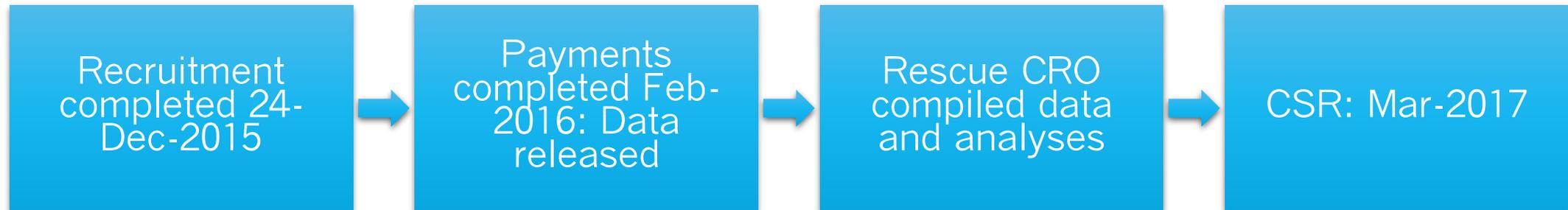
CRO – Contract termination and appointment of a rescue

- Balance required – Move fast, with compliance
- Cross-functional decision and vendor selection
- Risk management and mitigation – Internal conflicts
- Rescue CRO appointed within 3 weeks
- Administrator conflict – Primary CRO restricted
- RB terminated primary CRO contract effective end-2015
- Administrator conflict – Data held ‘hostage’ and communications cut
- ‘Human’ aspects of CRO team to consider
- Legal intervention, eCRF contract and payment required



The outcome

Conflicts and challenges successfully navigated



Impact on overall project timelines: 10 months

Recognition from senior stakeholders for rescuing a study with minimal impact

Learnings



- **Communication** – Consistent and lots of it
- **Financial oversight** – Know where and when Pass-Throughs and Site Fees are being distributed
- **Site oversight** – We were on top of operational status
 - Could leverage relationships despite Administrator blockages
 - Validated our approach – We still employ it now
- **Strengthened team** – Everyone pulled together
 - Flexibility within roles to overlap with each other
 - We all knew what needed to be done
 - We spoke with one voice to wider business
 - Good dynamics meant we avoided conflict amongst ourselves

Thank you



rb

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