



PROF KERRY WOOLFALL
AND
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**PARENTAL CONSENT
IN COMET**

**~50% OR LESS OF
TRIALS RECRUIT
TO TARGET**





Underpowered trials

Costly extensions or discontinuation of trials

Unnecessary burden on families for trials that close

Delay of evidence to improve treatments

FACTORS AFFECTING RECRUITMENT



TRIAL DESIGN, MANAGEMENT

SITE STAFFING, DATA COLLECTION PROCESS

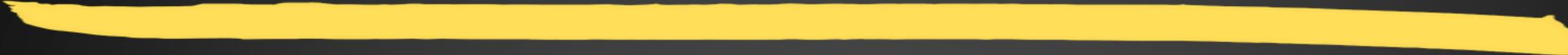
PATIENT/PARTICIPANT ATTITUDE TO RESEARCH, EXTRA TRAVEL

CLINICAL TEAM RESEARCH EXPERIENCE, MOTIVATION

INFORMATION AND CONSENT CLARITY, DYNAMICS OF RECRUITMENT INTERACTIONS

STUDY TEAM RESEARCH EXPERIENCE, COMMUNICATION BETWEEN STUDY TEAM MEMBERS AT SITE

FACTORS AFFECTING RECRUITMENT



SYSTEMATIC REVIEW OF 172 DISCONTINUED RCTS

28 DIFFERENT REASONS FOR RECRUITMENT FAILURE

89% OF THESE WERE PREVENTABLE

OVERESTIMATING OF ELIGIBLE PARTICIPANTS

**PREJUDICED VIEWS OF RECRUITERS AND PARTICIPANTS ON TRIAL
INTERVENTIONS**

FACTORS AFFECTING RECRUITMENT



COMMUNICATION OF INFORMATION HOW, WHEN AND WHO OF TRIAL INFORMATION DELIVERY

SIGNIFICANT TRIAL COMPONENTS BURDEN, RANDOMIZATION, FINANCIAL INCENTIVES

INFLUENCE OF OTHER PEOPLE FAMILY, FRIENDS, AND PROFESSIONAL, MEDIA, ONLINE

RISKS AND BENEFITS BALANCING “WHAT HAVE I GOT TO LOSE?” WITH “WHAT HAVE I GOT TO GAIN?”

PERSONAL BENEFITS NEW TREATMENT, IMPROVED CARE, ALTRUISM, HELPING OTHERS, CURIOSITY.

FACTORS AFFECTING RECRUITMENT



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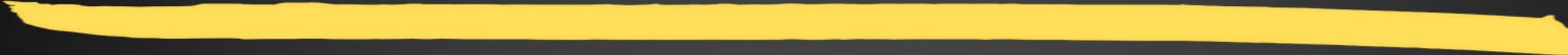
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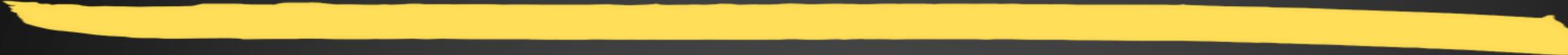
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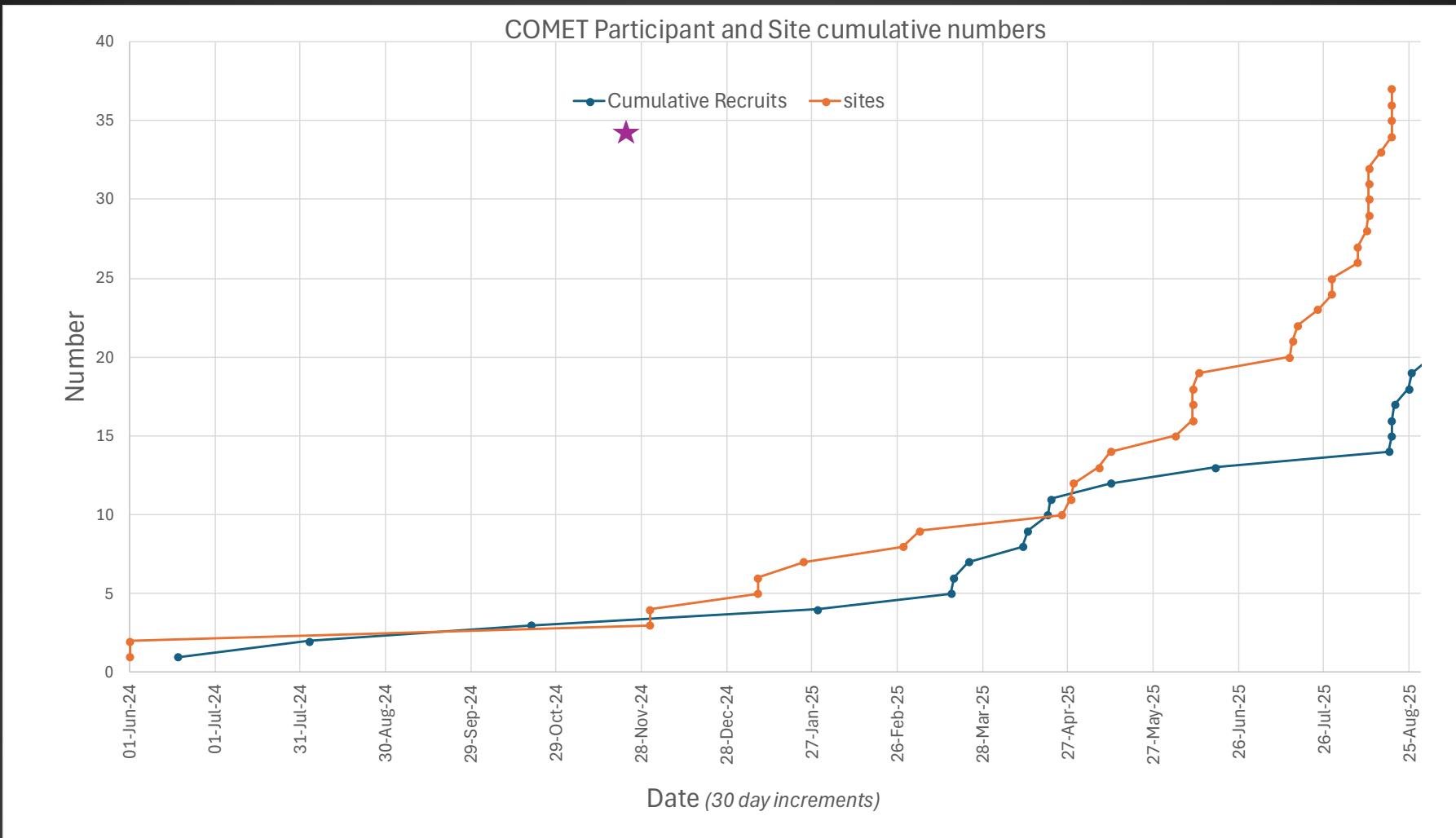
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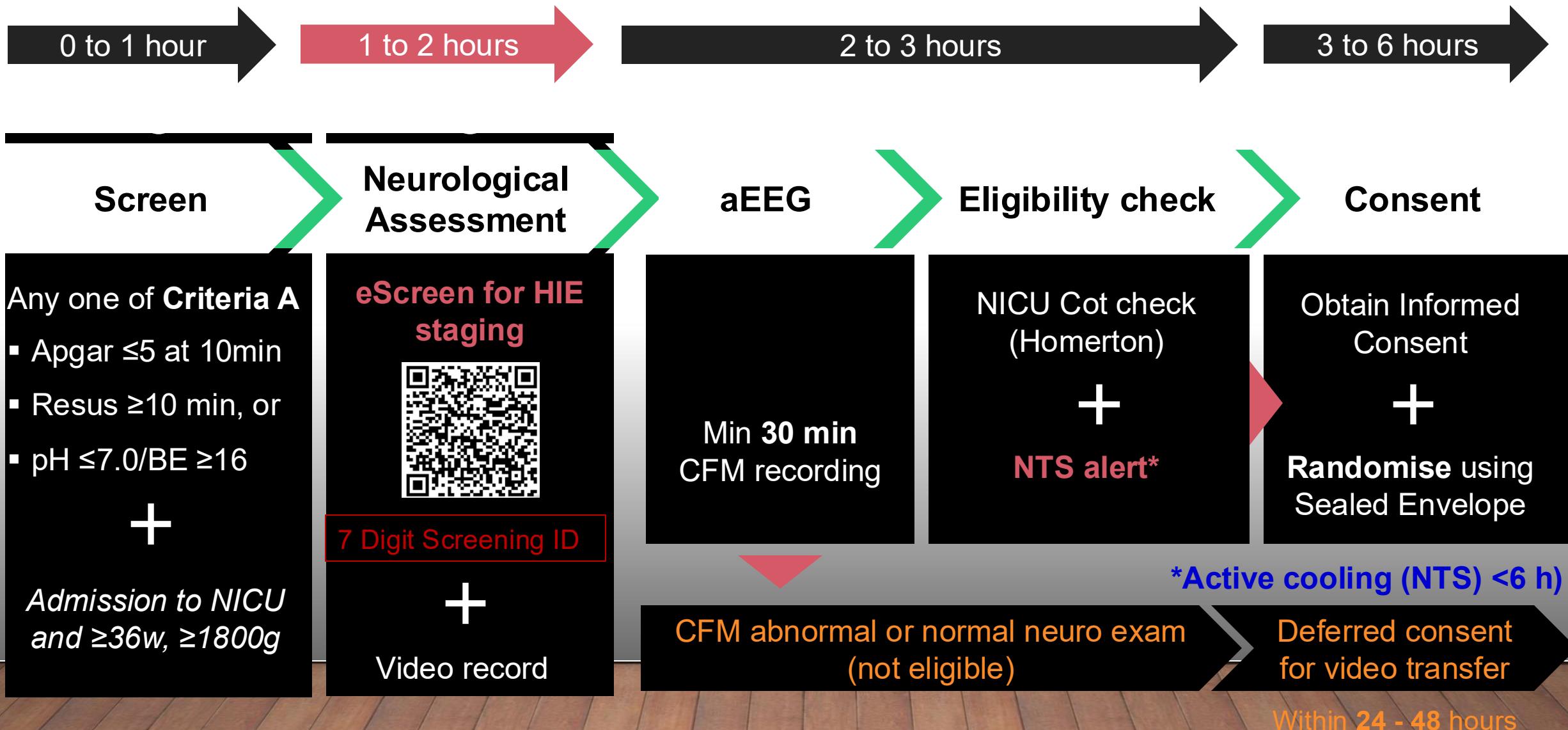
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BEFORE RANDOMISATION



CHALLENGES

FACTOR

- **Significant trial components**
- **Staff perceptions**
- **Risks and benefits**
- **Communication**



INFORMAL FEEDBACK

- Concerns about separation- transfer to different unit (twins)
- Difficulties in approaching within the timeframe
- When an eligible baby is looking 'ok' concerns about cooling (parents/doctors)
- Length of participant information sheet
- Terminology 'mild'

YOUR VIEWS

- What do you think are the barriers to recruitment in COMET
- What do you think could help improve recruitment?