

PROF KERRY WOOLFALL
AND
DR STUTI PANT

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, RATIONIZATION, FINANCIAL INCENTIVES

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

RISKS AND BENEFITS BALANCE OF “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

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

SIGNIFICANT TRIAL COMPONENTS BURDEN, RANDOMIZATION, FINANCIAL INCENTIVES

INFLUENCE OF OTHER FACTORS FAMILY, FRIENDS, HEALTH CARE PROFESSIONAL, MEDIA, ONLINE

RISKS AND BENEFITS BALANCE OF “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

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

SIGNIFICANT TRIAL COMPONENTS BURDEN, RANDOMIZATION, FINANCIAL INCENTIVES

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

RISKS AND BENEFITS BALANCE OF “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

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

SIGNIFICANT TRIAL COMPONENTS BURDEN, RANDOMIZATION, FINANCIAL INCENTIVES

INFLUENCE OF OTHER PEOPLE FAMILY, FRIENDS, HEALTH 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

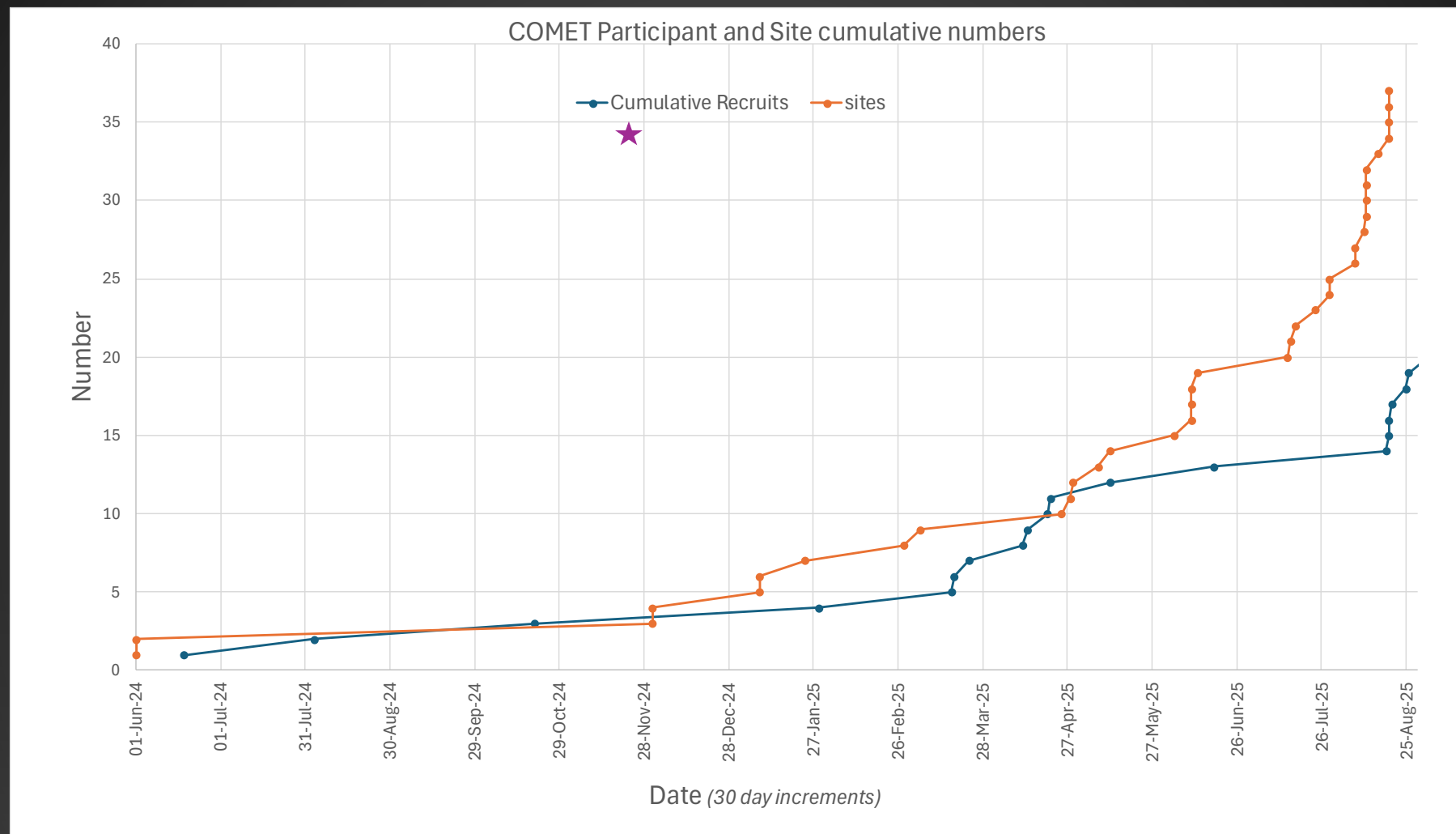
COMMUNICATION OF INFORMATION HOW, WHEN AND WHO OF TRIAL INFORMATION DELIVERY

SIGNIFICANT TRIAL COMPONENTS BURDEN, RANDOMIZATION, FINANCIAL INCENTIVES

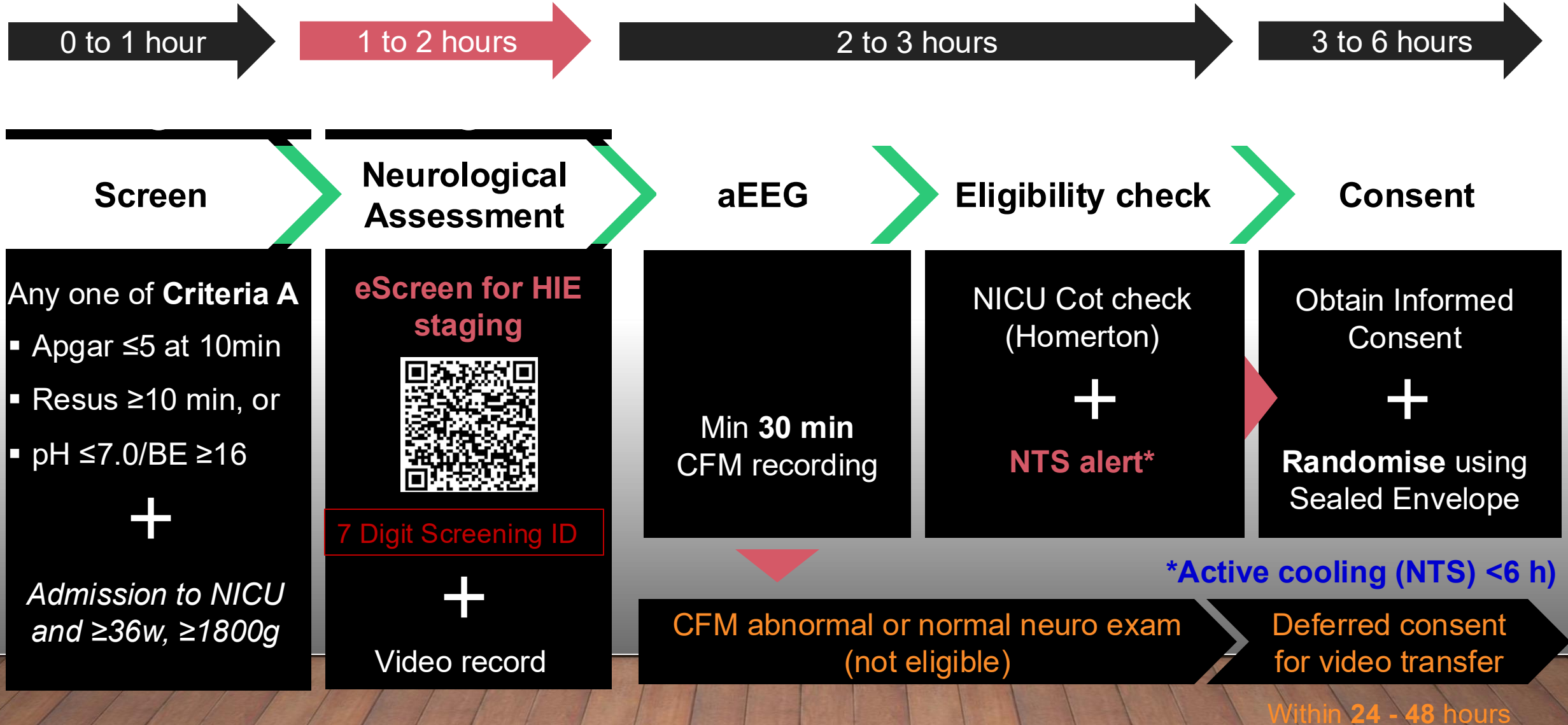
INFLUENCE OF OTHER PEOPLE FAMILY, FRIENDS, HEALTH PROFESSIONAL, MEDIA, ONLINE

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

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



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?