PREDICT Paediatric Research in Emergency Departments International Collaborative

Study education

PCCRG Paediatric Critical Care Research Group

PREDICT Paediatric Research in Emergency Departments International Collaborative

Study start-up PARIS

Start with the idea!

Then the question to be asked?

PREDICT Paediatric Research in Emergency Departments International Collaborative

Study start-up PARIS

- Question outlined
- Protocol
- NEAF
- Ethics
- Governance/centre
- Centres commence recruiting
  - ❖ Logistics – site visits & key staff
  - ❖ Educational resources
    - Face-to face education
    - Champion booklet
    - Signage
    - Lanyards

PREDICT Paediatric Research in Emergency Departments International Collaborative

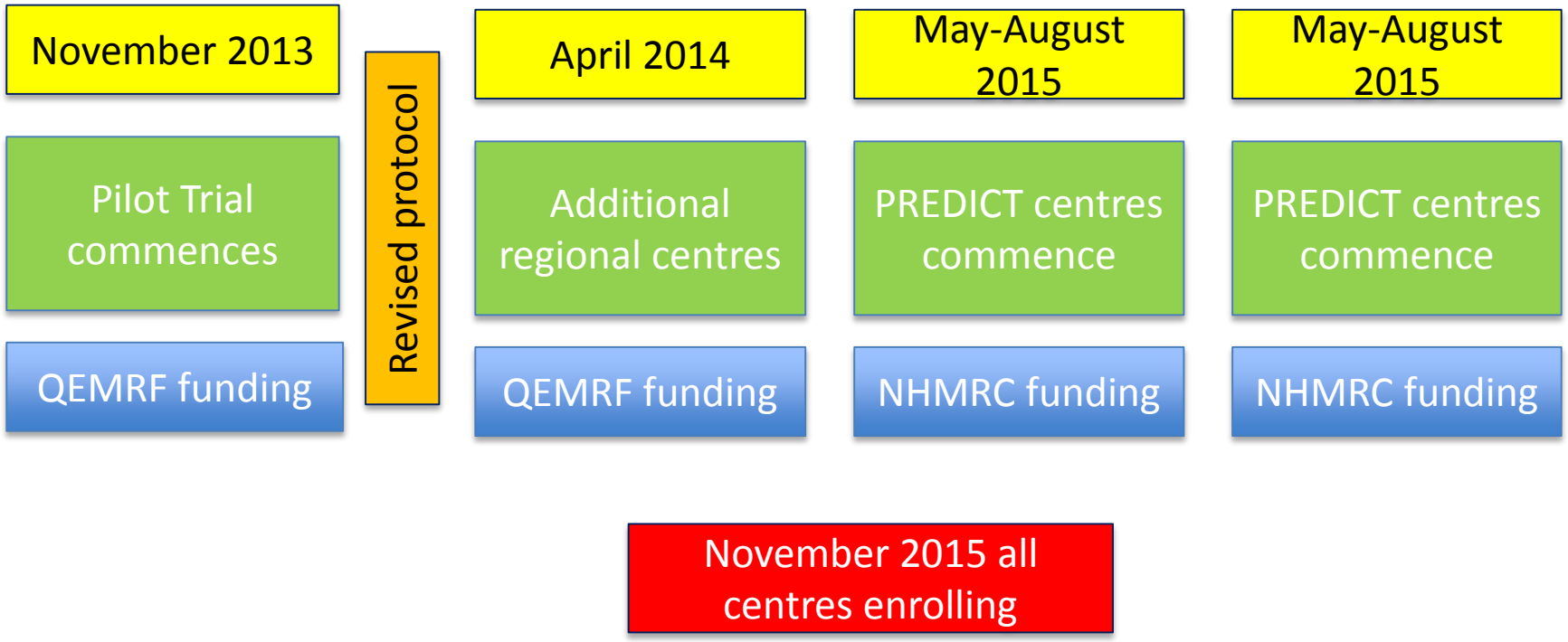
Study start-up PARIS

- Funding to commence pilot trial
- Communicate/Collaborate with regional centres in first year to gain involvement
- Commence regional centre with pilot trial
- Apply further funding (QEMRF/NHMRC/others)
- Obtain other centres (PREDICT) = 17

PREDICT Paediatric Research in Emergency Departments International Collaborative

Study start-up PARIS

2 years to have 17 centres recruiting



PREDICT Paediatric Research in Emergency Departments International Collaborative

Study start-up PARIS

Monitoring and maintaining study progress thereafter

PREDICT Paediatric Research in Emergency Departments International Collaborative

Study start-up BellPIC

Background:

- Retrospective audit on Bell's Palsy over 2 years
- Allowed us data to submit to NHMRC project grant applications
- Funding application successful
- 6 months: Design of protocol and all study documents, including CRF's, PICF, education tools, pharmacy procedures
- HREC and governance approvals, CTRA, TGA

PREDICT Paediatric Research in Emergency Departments International Collaborative

Study start-up BellPIC

Study Start Up:

- Visit sites prior to starting recruitment
- Allow RA's to travel to RCH to education re: study
- Study day to outline study "train the trainer"

- Monitoring progress: Regular teleconferences, yearly site audits.

PREDICT Paediatric Research in Emergency Departments International Collaborative

ConSEPT: Convulsive Status Epilepticus Paediatric Trial: **Study Start Up**

PREDICT Paediatric Research in Emergency Departments International Collaborative

The Beginning

- Protocol – first
- Double-Blinded, double armed, randomised, controlled trial. Placebo arm vs treatment arm
- Funding- HRC NZ
- Feb 2012-Feb 2015
- Ethics – NZ, Australia, NEAF, WA,SA
- Legal agreements
- TGA(Therapeutic Goods Administration) Aus
- SCOTT (Standing Committee on Therapeutic Trials)NZ

PREDICT

PREDICT Paediatric Research in Emergency Departments International Collaborative

Ethics

- 2 Countries
- 4 Ethics Committees
- 13 site specific ethics

PREDICT

PREDICT Paediatric Research in Emergency Departments International Collaborative

Legal Agreements

- CTRA's 13 sites, 13 research departments, 13 legal teams, 13 agreements.
- TGA TGA(Therapeutic Goods Administration) Aus
- SCOTT (Standing Committee on Therapeutic Trials)NZ

PREDICT

PREDICT Paediatric Research in Emergency Departments International Collaborative

Site Visits

- 2013 – Visited all sites, met with teams
- Insight into each department

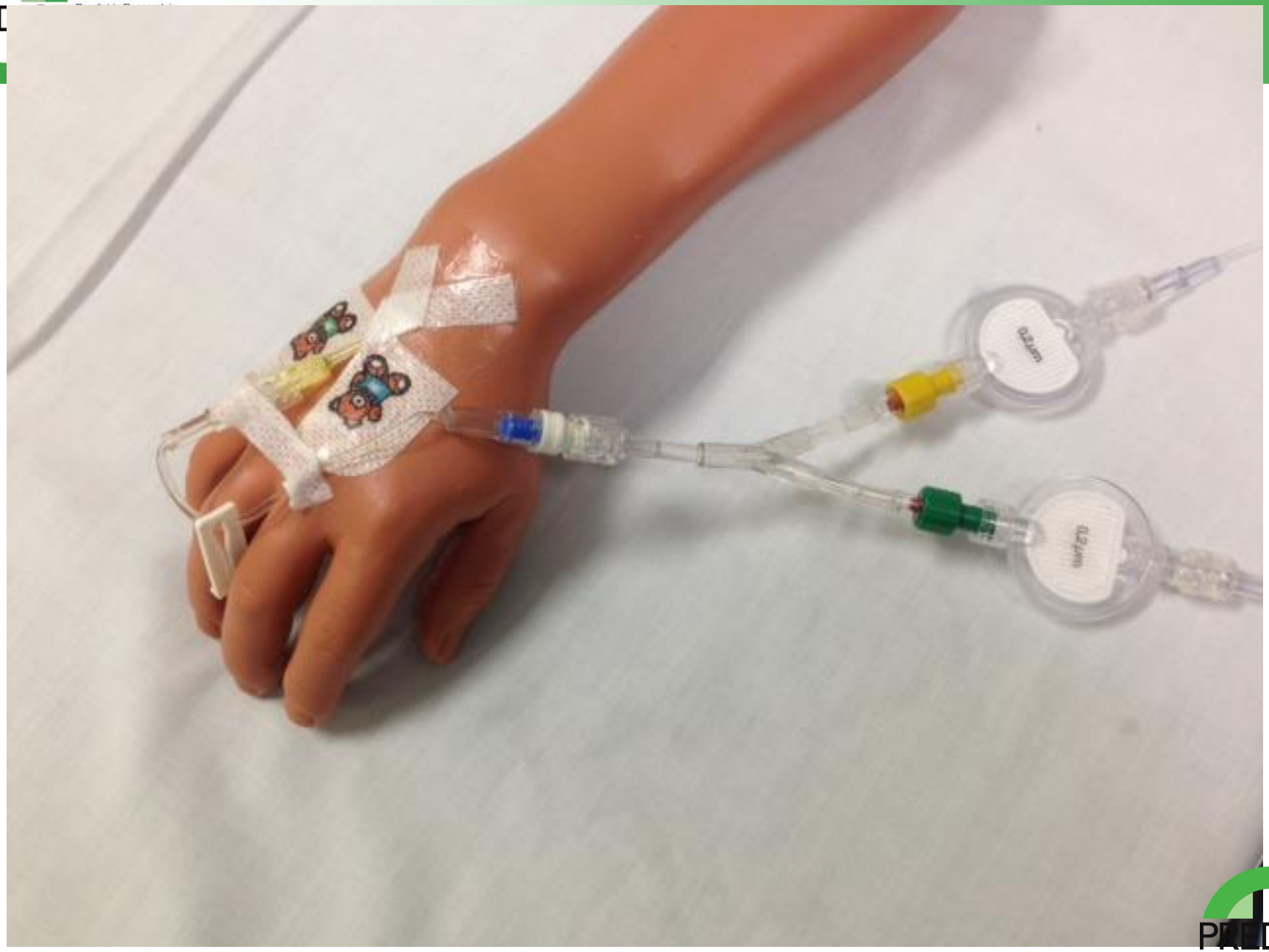
PREDICT

PREDICT Paediatric Research in Emergency Departments International Collaborative

Initial Protocol Outline

- Double-Blinded, randomised, controlled trial. Placebo arm vs treatment arm: double-arm process.

PREDICT

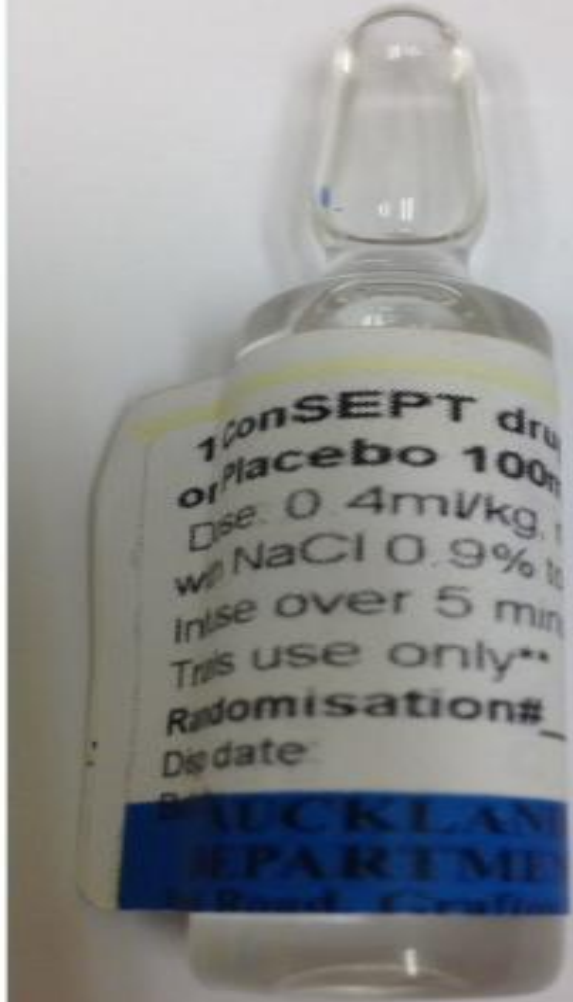



ON HOLD
150 ml/h
1.00 mg/kg/min
+ ADJUST -
Phenytoin
VOLUME
0.00 ml
0.00 mg
VOLUME
VTBI
Alaris
GH
MEDICATION ADDED
DRUG
AMOUNT
ASD155
RETURN TO EQUIPMENT POOL
Levetiracetam Trial
Magnesium Ritha
Meropenem
Metronidazole
Naloxone
DRUG
SELECT
OK
CAN
GH

A1


ConSEPT
Placebo
Dose: 0.4ml/kg
with NaCl 0.9%
Infuse over 5 min
Trials use only**
Randomisation#
Disp date

B1


ConSEPT
Placebo
Dose: 0.4ml/kg
NaCl 0.9%
Trials use only**
Randomisation#
Disp date

Drug Manufacture Issues – 2 year process

- Drug Manufacture
- Identical vials and ampoules of placebo to match levetiracetam and phenytoin
- Company Canberra sourced
- We purchased a new vial machine
- Sterility issues with vials
- UK company

PREDICT Paediatric Research in Emergency Departments International Collaborative

cont.

- UK company to make vials
- Long process
- Period of absence
- Company lost license
- Temporarily
- 3 months
- Company went into receivership

PREDICT

Change of Protocol

- A new protocol developed
- Easier to follow

But….

The process began all over:

- New Ethics
- New Agreements
- New education

PREDICT Paediatric Research in Emergency Departments International Collaborative

TGA

- Change of process
- Decided NZ could not be sponsor
- Each site to be own sponsor
- Online submission
- No access to NZ
- TGA redone

PREDICT

PREDICT Paediatric Research in Emergency Departments International Collaborative

Gradual

2015

- 11 sites commenced

2016

- 1 further site commenced
- 1 awaiting
- 1 new site to add 1 more country, 1 more ethics application, 1 more legal agreement

"WHAT WE'RE LOOKING FOR IS SOMEONE, WHO, OVERWORKED AND UNDERPAID WILL STILL BE SMILING AT THE END OF A GRUELING DAY."