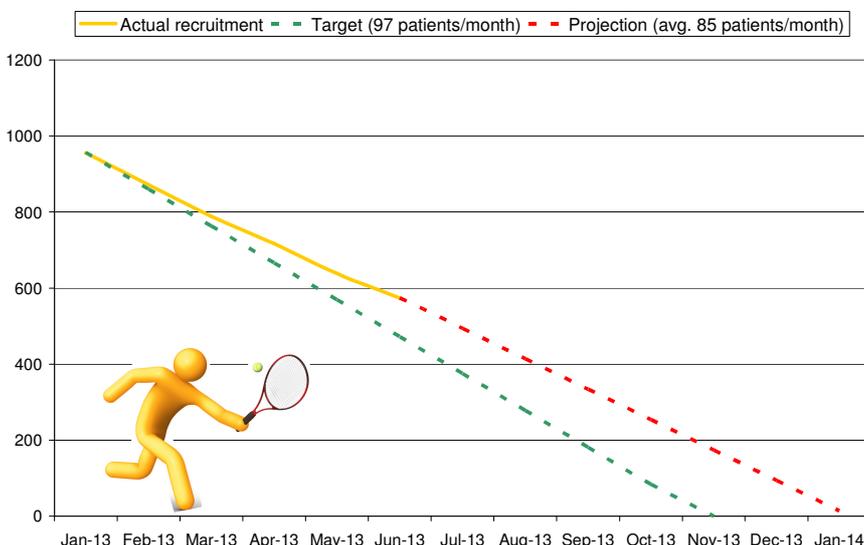


## CALORIES reaches quarter finals...!

**With 1842 patients recruited, we are over three-quarters of the way towards our target of 2400 patients!**

The graph shows current recruitment (average: 85 patients per month) against the target (97 patients per month) during 2013.

As you can see, we are slightly behind and based on the current rate of recruitment we should be finished by January 2014. The 'ace' is on to finish by our target of November 2013!



## Top seeds

Well done to the top recruiting sites between March and May 2013.

Musgrove Park Hospital	20
St Thomas' Hospital	18
St Mary's Hospital London	17
Poole Hospital	16
The Royal Blackburn Hospital	14
University College Hospital	13
Addenbrooke's Hospital	12
University Hospital of North Staffordshire	12
Queen Alexandra Hospital	11
Bristol Royal Infirmary	10
Royal Hampshire County Hospital	10



Congratulations to Musgrove Park Hospital who top the list this quarter!



## Player's debut

Welcome to...

### Southampton General Hospital

...who have recently opened to recruitment.

We now have 25 sites open and recruiting!

## Serving the intervention

Patients should receive nutritional support – via the parenteral or enteral route – for 120 hours. Switching a patient from parenteral to enteral or from enteral to parenteral within the 120 hours is a protocol violation and should be reported to the ICNARC CTU ([calories@icnarc.org](mailto:calories@icnarc.org)). A File Note should be written to explain the reason for the violation and entered into the Comment box on the web portal.



## Retrospective consent

Please remember to obtain retrospective consent as soon as possible after the patient regains mental capacity prior to discharge from hospital. If a patient is known to have regained mental capacity and is discharged without providing retrospective consent, they should be followed up either by telephone or at a follow-up clinic or out-patient appointment.

See SOP 006: Consent Procedures (v1.4, 27/09/2012) for further guidance.



# Game, dataset and match

Recently a spreadsheet was emailed to sites listing missing data (by patient trial ID) for the following fields:

- Baseline – Physiology/Interventions;
- Daily – Nutritional support;
- Daily – Physiology/Interventions; and
- Safety Monitoring – Adverse Events.

Please enter missing data directly onto the web portal. You should ignore queries if you have already provided an explanation for missing data in the comments box on the web portal. Please contact [calories@icnarc.org](mailto:calories@icnarc.org) if you have any questions.

## International Clinical Trials Day

International Clinical Trials Day is celebrated every year on 20 May to commemorate the first clinical trial, conducted by James Lind in 1747.



This year, the NIHR launched the “It’s ok to ask” campaign which is aimed at encouraging patients and their carers to ask their doctors about clinical research and whether it is right for them. Whilst the

main part of the campaign will be patient-focused, the NIHR is also calling upon individual researchers and research groups to show that they back the drive to empower patients in clinical research. You can find out more about the campaign at [www.crncc.nihr.ac.uk/oktoask](http://www.crncc.nihr.ac.uk/oktoask).

The ICNARC CTU decided to celebrate this year’s International Clinical Trials Day with the Cupcake Trial...! Staff at ICNARC who consented to take part, were randomised to one of two bakers’ cupcakes (designs were based on our current trials – you should recognise at least one of them...!). Participants were asked to complete an evaluation form, ranking the cupcakes from 1 (poor) to 4 (excellent) on presentation, taste and crumb structure.

The CALORIES cupcakes scored highly on presentation and taste.



## Tour date

### Monthly teleconference

22 August 2013, 13.00 - 14.00

Open to everyone, please dial-in and join us

# FAQs



**Q. Are patients at risk of re-feeding syndrome eligible for CALORIES?**

A. Patients at risk of re-feeding syndrome are not excluded from CALORIES. If the patient fulfils the eligibility criteria and the Trial Protocol can be followed (for five days) with the aim of feeding patients to a target of 25 kcal per day within 48-72 hours, the patient can be recruited into the trial. However, if the patient is considered to be at high risk of re-feeding syndrome and you would not be able to deliver nutritional support as per the protocol, then the patient should not be recruited.

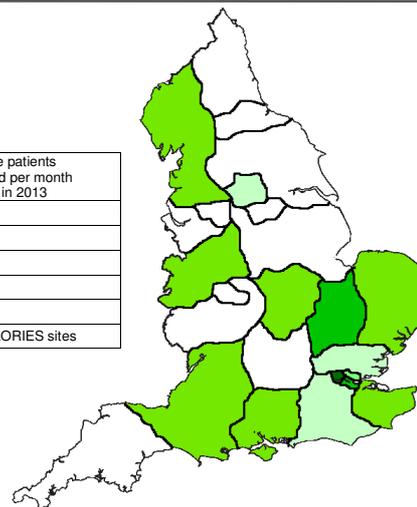
**Q. Can someone other than the Principal Investigator (PI) sign Serious Adverse Event (SAE) reports?**

A. Yes, the PI can delegate responsibility for assessing SAEs, including signing the SAE report, to a (medically qualified) member of the team. Ultimately, it is the responsibility of the PI to review all SAEs at their site.

## Hitting the net (work)



AVG	Average patients recruited per month per site in 2013
>5.0	>5.0
4.0-4.9	4.0-4.9
3.0-3.9	3.0-3.9
2.0-2.9	2.0-2.9
<1.9	<1.9
	No CALORIES sites



Congratulations to London (North West), the highest recruiting CLRN in 2013, closely followed by West Anglia and London (South) CLRNs.

Thank you to all sites for your continued hard work in making CALORIES such a success!

## Contact us

### General enquiries

Email: [calories@icnarc.org](mailto:calories@icnarc.org)

Tel: 020 7269 9277

Fax: 020 7831 6879

### 24/7 clinical support line

Tel: 020 7269 9290

### SAE reporting to ICNARC

Fax: 020 7831 6879

