

Meeting the needs of industry in DeNDRoN: local strategies, national results

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Introduction

Ensuring the NHS can meet the health research needs of industry is one of the key aims of the NIHR Clinical Research Network. This poster describes the approach taken to this in one of our Local Research Networks; and the impact of new sites and national planning on a particular trial.

"Again many, many thanks for the UKCRN/ Dendron support. I have to confess your network is working far far better than others over the world"

Emmanuel Tamches,
Medical Director, Debiopharm

"Thank you - that was quick!"

Debbie Mitchell,
Feasibility Specialist, Pfizer Ltd

Case study 1

Developing local capacity and expertise in order to deliver on time to the highest standards in the North West

North West DeNDRoN has participated 18 commercial trials since 2007: 10 dementia; 6 Parkinson's disease and 2 Huntington's disease.

Our strategy is to ensure:

- Available site capability information for Expressions of Interest/feasibility i.e. patient populations/pathways
- Sound knowledge and experience across the Network working with Trusts, R & D departments and clinicians-educating colleagues and integrating research within services-working together as team
- Early development of good working relationships with commercial sponsors
- Fully trained personnel available including Study Co-ordinator
- Significant resource available during set up and study commencement

"...I have found the DeNDRoN staff to be very organised, highly motivated and experienced. Always quick to identify recruitment problems."

INC Research

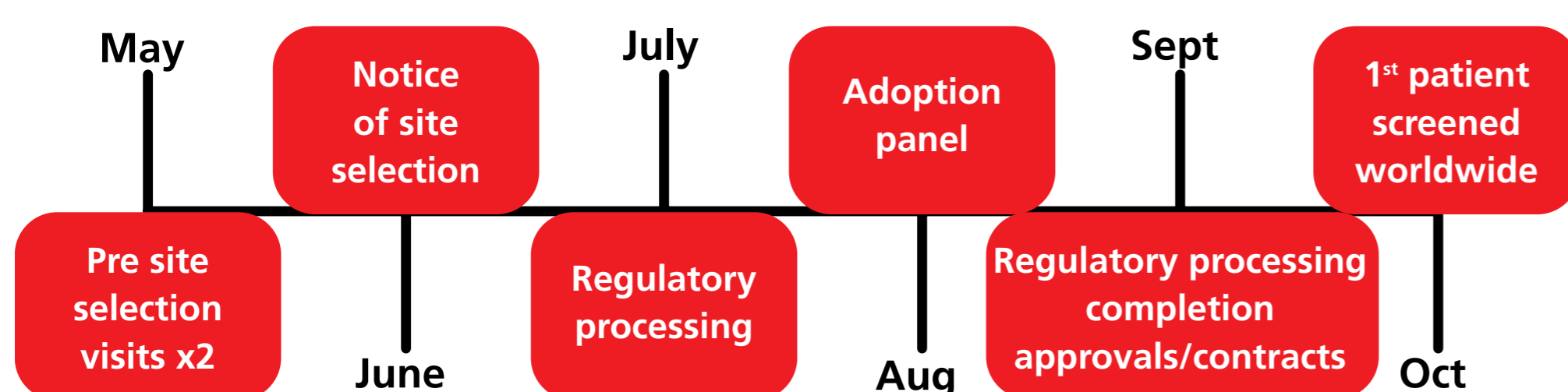
"It has been good to have someone who you can contact at the sites who you know will get answers for you quickly. The contract at Dr Leroi's site was a great example of how a team works well together"

Abbott Laboratories

Example timeline:

DeNDRoN 040, a randomised, double-blind, placebo and active-controlled, parallel group study to evaluate the efficacy and safety of ABT-126 in subjects with mild to moderate Alzheimer's disease.

Figure 1: Timeline for DeNDRoN 040



Challenges:

- Integrating with new developing clinical service which will provide patient pool but
- Two NHS Trusts involved in regulatory processing/approvals for clinical trial
- Ensuring large enough research team in place to deliver
- Working with new systems-CSP, Costing Template

"...the study data were complete and of high quality (recruitment, organisation and reactivity), confirming the commitment and professionalism of DeNDRoN NW"

Debioclinic

Case study 2

Developing new investigator capacity and coordinating nationally to ensure delivery on time to target

Trial: DeNDRoN 009

- A multi-centre, double-blind, double-dummy, placebo-controlled, parallel group, randomised, phase IIb proof of concept study with 3 oral dose groups of study drug or Donepezil during 12 weeks treatment in patients with Alzheimer's Disease
- Chief investigator and 4 of 7 UK sites identified through DeNDRoN, 2 of which were sites new to commercial research
- Despite one of our new sites being first to randomise a patient internationally, after 4 months DeNDRoN identified a significant risk of failing to deliver to target on time
- Recovery Plan developed and implemented between Sponsor, CI and DeNDRoN

"This is a fantastic achievement for a study to which it has been very difficult to enrol. Thank you to all the site staff, DeNDRoN support and the study team for the continuous drive to deliver this result."

Joan Thomson,
Clinical Project Leader, AstraZeneca

Outcomes:

- Intervention through Recovery Plan led to sharp increase in recruitment rate (figure 2)
- New sites identified and supported by DeNDRoN LRNs outperformed more experienced sites and NHS site without DeNDRoN support unable to recruit any patients (figure 3)
- UK target (31) reached in abbreviated recruitment window

Figure 2: Cumulative number of patients randomised in the UK

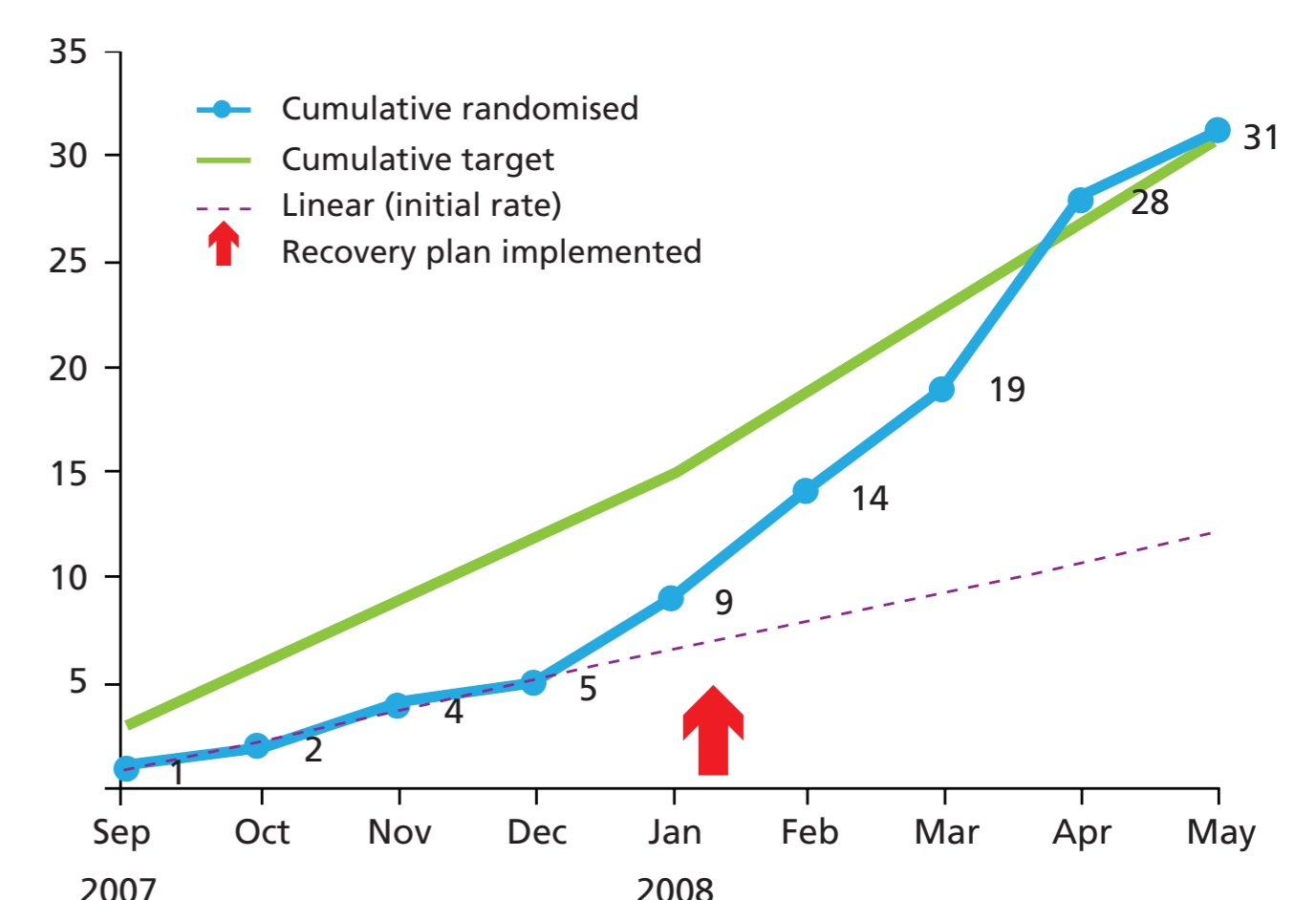
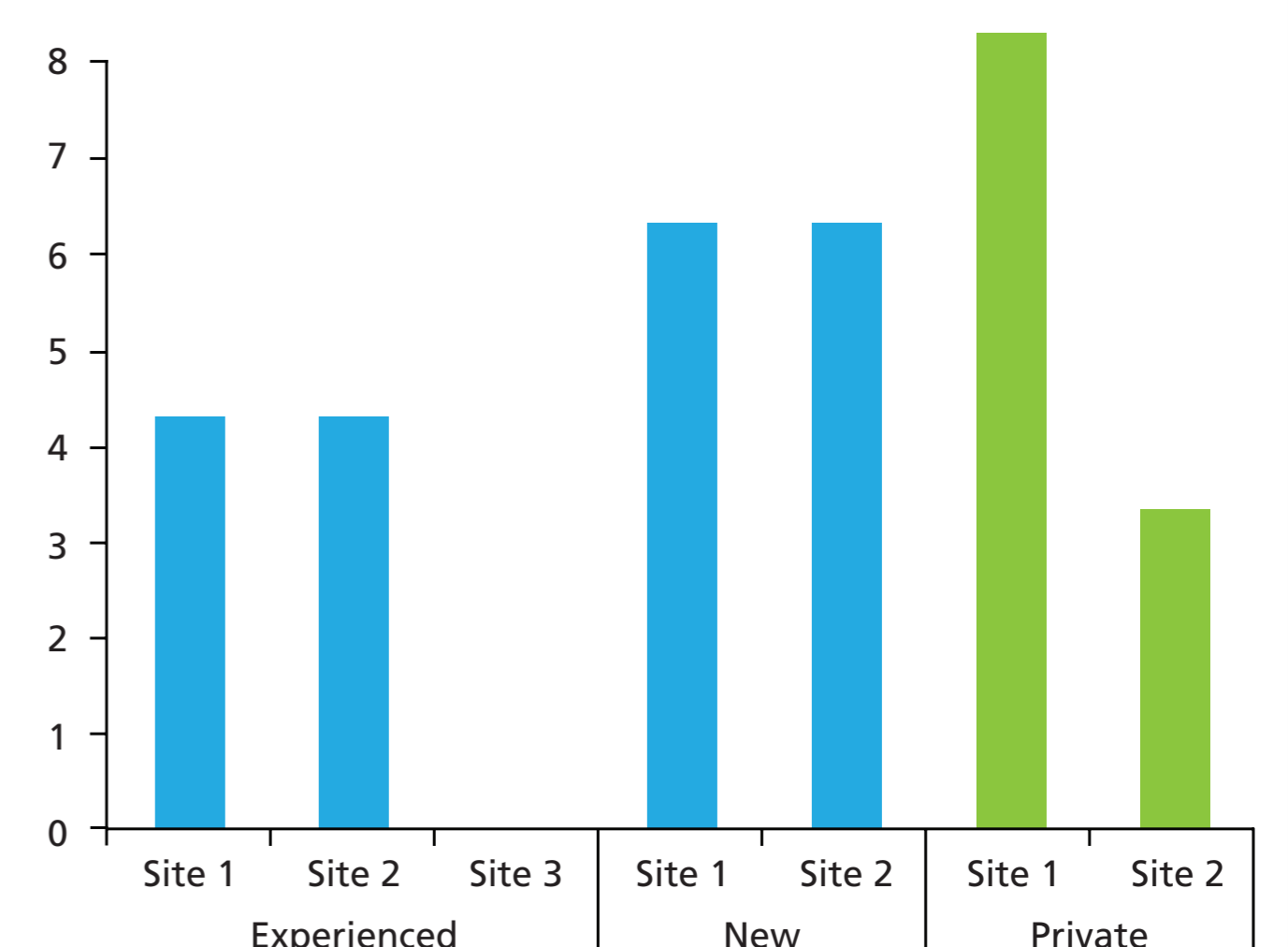


Figure 3: Total patients randomised in each UK site



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