

Exploristics offers a suite of innovative predictive modelling modules for use in the design and implementation of clinical trials. The suite is built using a common analytic platform and has been validated using data from many trials. It will be of benefit to pharmaceutical companies, CROs and others wishing to maximise the output of their trials whilst minimising costs.

### Patient Recruitment Module

#### The Problem

Patient recruitment is very costly and a well-recognized bottleneck in designing/monitoring clinical trials. More than 60% of studies fail to recruit in time and many are based on deterministic models for recruitment that do not account for uncertainties, variation or fluctuation in recruitment assumptions.

#### Key Features

- Computes the mean and confidence bounds for the number of recruited patients over time and for the total recruitment time at any stage of the trial using interim data
- Evaluates the optimal number of centres needed to complete recruitment in time with a given confidence
- Utilises stochastic processes modelling, statistical estimation, Bayesian re-estimation, asymptotic approximations, predictive modelling.

#### Case Study: Predicting, planning and adjusting recruitment

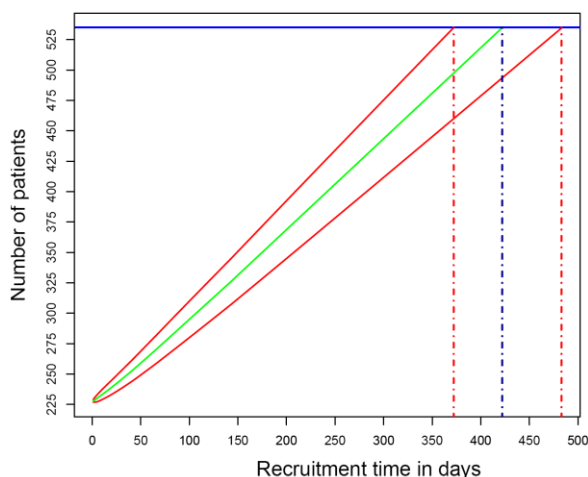
During the conduct of a study we have the following information:

- Duration of active recruitment and the number of recruited patients for each site;
- 535 – target of the total number of patients to be recruited;
- 227 – number of already recruited patients; 131 -- number of currently active sites;
- 32 – number of new sites to be initiated in the future.

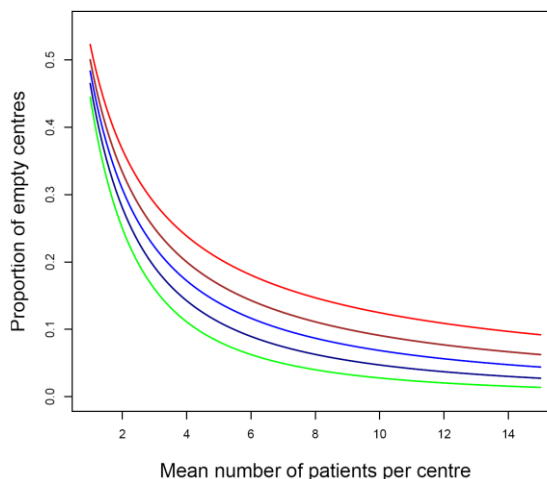
#### Results and Conclusion

Fig 1 shows the mean time and 90% prediction interval to reach 535 pts [422 (372, 483)]. The tool can predict the number of empty (or low performing) centres for any particular recruitment scenario (Fig 2). If on average 4 pts/centre, then there may be ~15-20% empty centres.

**Fig 1** Predicting recruitment in time with 90% bounds



**Fig 2** Proportion of the number of empty centres



#### Outcome

The tool dramatically improves the accuracy of prediction and widely extends opportunities for recruitment planning/adjustment. This drastically reduces cost relating to prolonged recruitment times and to maintaining sites that do not recruit.