



PATIENT CARE
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IRISH PHARMACEUTICAL HEALTHCARE ASSOCIATION

Attracting Clinical Trials To Ireland - Insights From The Pharmaceutical Industry

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Mansion House, Dublin



Overview

- Clinical Trials Performance - Our Shared Ambition
- The IPHA survey of members
- How can we attract more trials?
- Questions and Answers



Clinical Trials Performance - Our Shared Ambition



Ireland Can Have a Lead Role for Clinical Trials in Europe

- Clinical trials have a key role in evaluating the safety and effectiveness of a medicine
- They can save lives and improve the standard of patient care
- A strong clinical trials infrastructure gives patients access to often life-saving trials
- Ireland is not as strong a location for trials in comparison to similar-sized countries such as Denmark
- We have recommendations for strengthening Ireland's attractiveness – a shared ambition!



IPHA Survey

Clinical Research Executive Group (CREG)



Survey Purpose

- Baseline our current performance with start-up activities
- Explore the number and spread of trials
- Investigate the time it takes to get a site ready to recruit
- Identify whether sites are meeting their recruitment commitments

This will help us to...

- Gain an understanding of recent performance in terms of start-up speed and ability to deliver recruitment targets
- Identify roadblocks, quantify the extent of delays and propose policy recommendations
- Quantify a baseline to set and measure future targets against



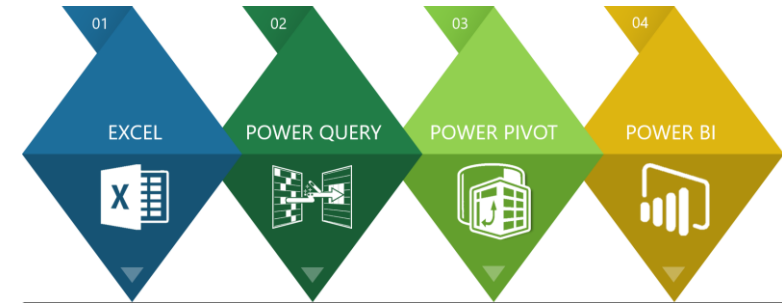
Focus of CREG Survey

- Quantify and compare performance of nine metrics from 2013-2018
 - Six start-up metrics measuring days between eight pre-defined dates
 - Three recruitment metrics measuring % recruitment achieved



Data Collection

- Survey was designed to capture standard dates associated with initiating a clinical trial and recruitment metrics
- Survey data received from 14 companies totaling 189 clinical trials (to varying degrees of validity/completion)
- Data collection took place in November 2018
- Companies and trial brand anonymized
- Data was cleaned and validated
- A data model was created to explore trends



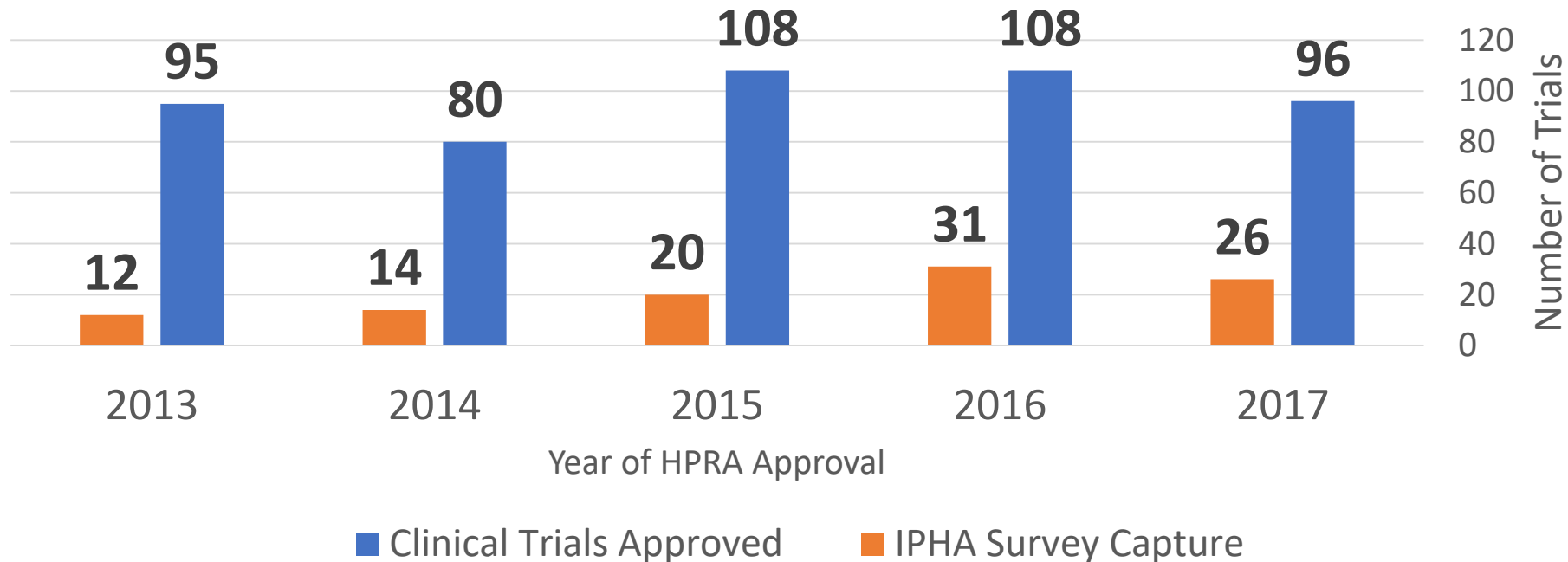
Responses From IPHA Membership

Received or Included	/Out of Total	%Response/Completion Rate
Email Responses Received	Total Prescription Division Members	
18	39	46%
Responses With Surveys Completed	Total Responses Received	
14	18	78%
Responses With Surveys Completed	Prescription Division Members (Excl. Nos)	
14	34	41%
Responses with survey data above valid threshold for inclusion	Total Responses With Surveys Completed	
11	14	79%
Number Top 10 Global based on 2018 Revenue	Total Responses with survey data above valid threshold for inclusion	
7	11	64%



Sample Population Captured Is Just An Initial Snapshot

IPHA Survey Data Sample Capture

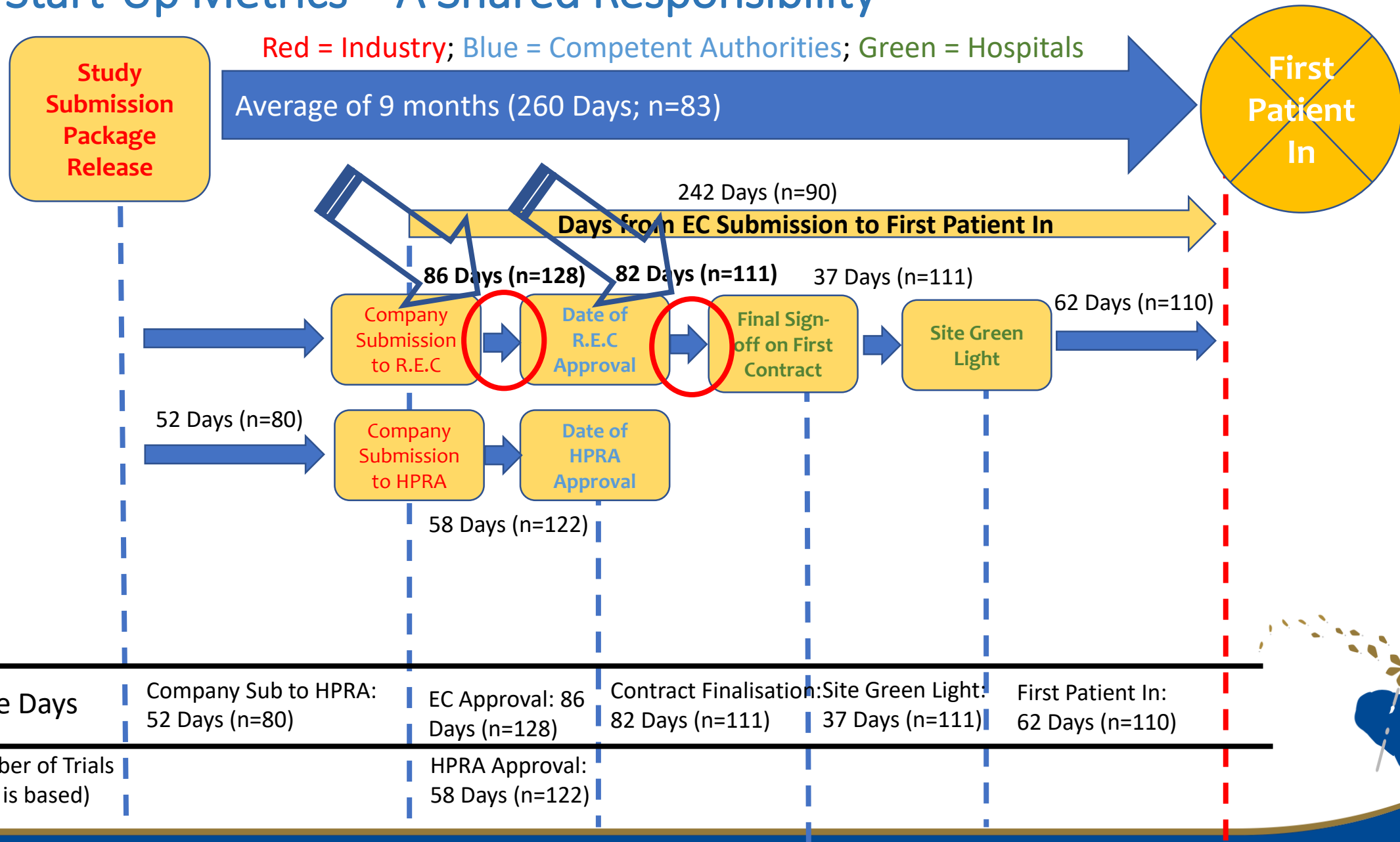


Results

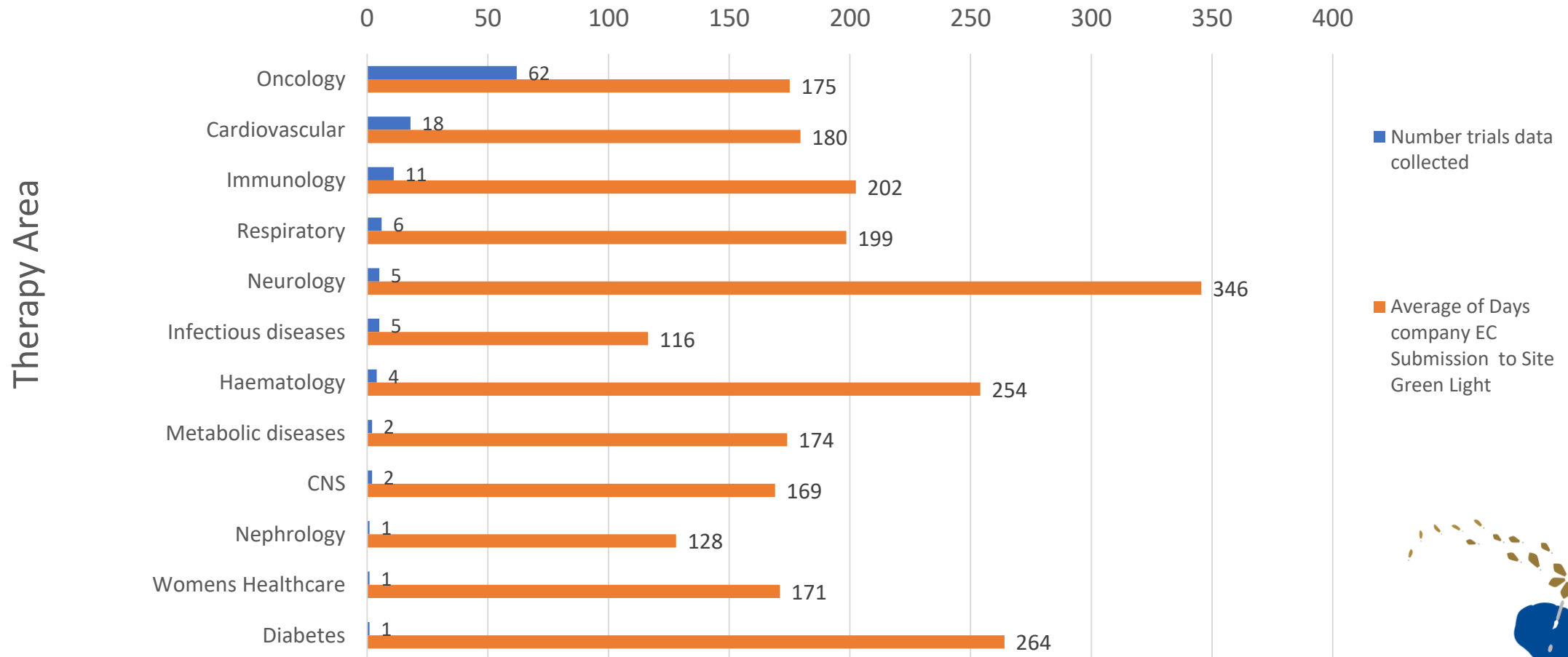
A. Start-Up Metrics



Trial Start-Up Metrics – A Shared Responsibility

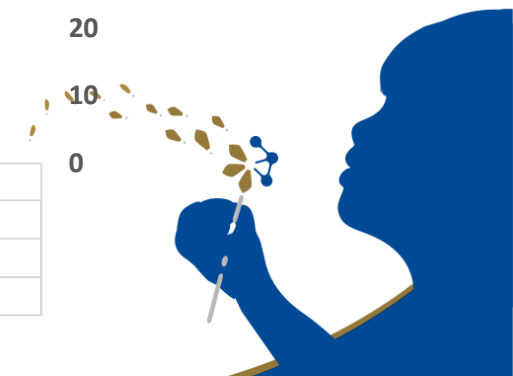
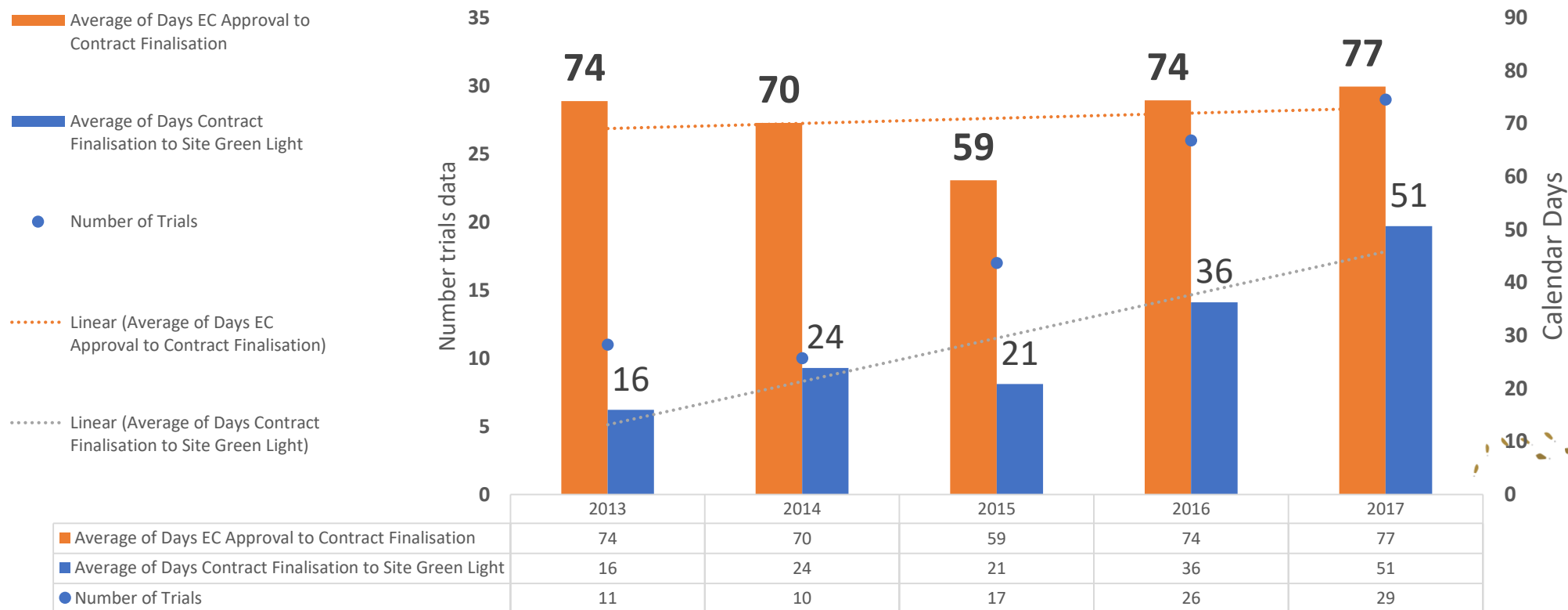


Variations in Approval Timings From Ethics Committee Submission to Site Green Light



Increasing Trend in Post Ethics Approval Days

Days Post EC-Approval to Site Green Light

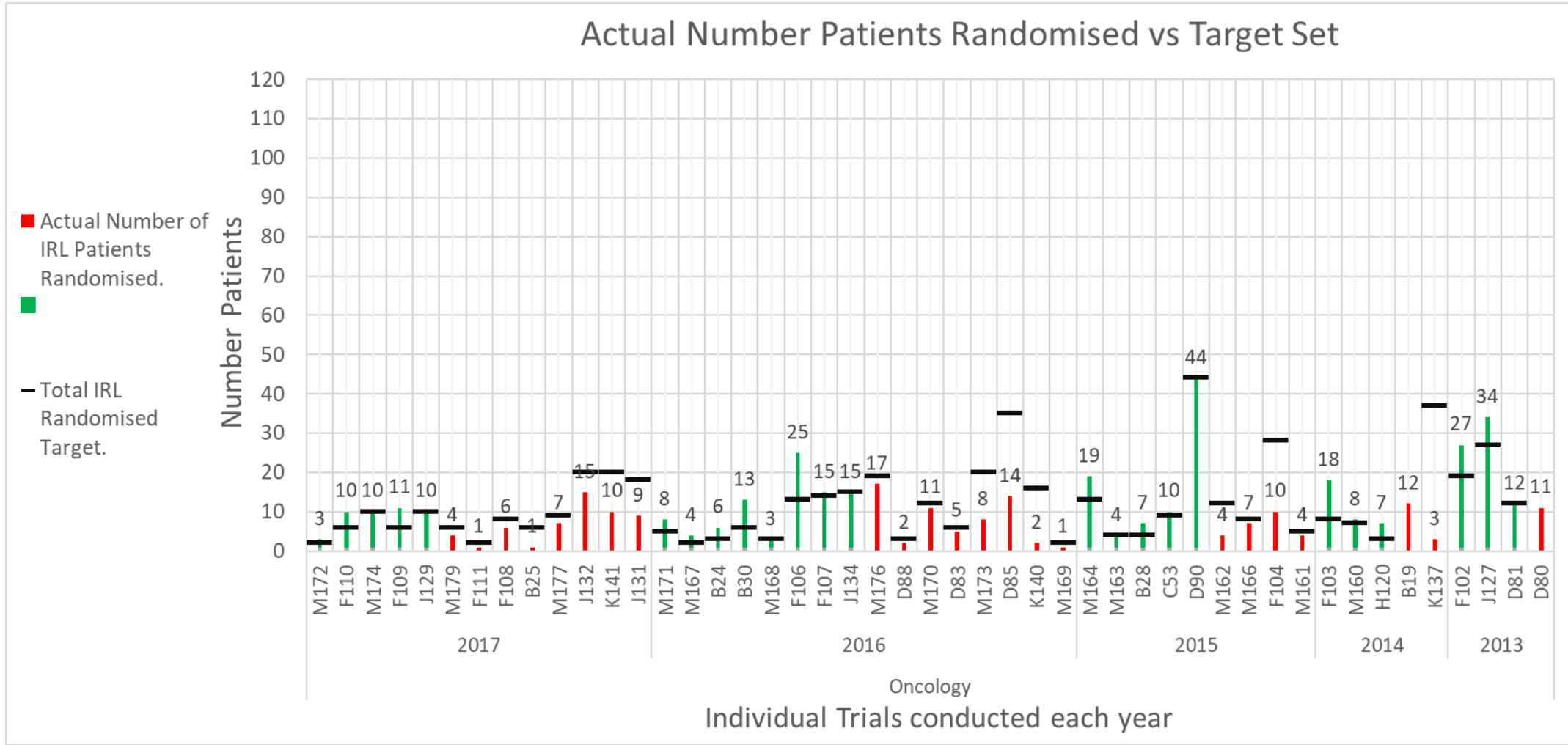


Results

B. Recruitment Metrics by Therapeutic Area

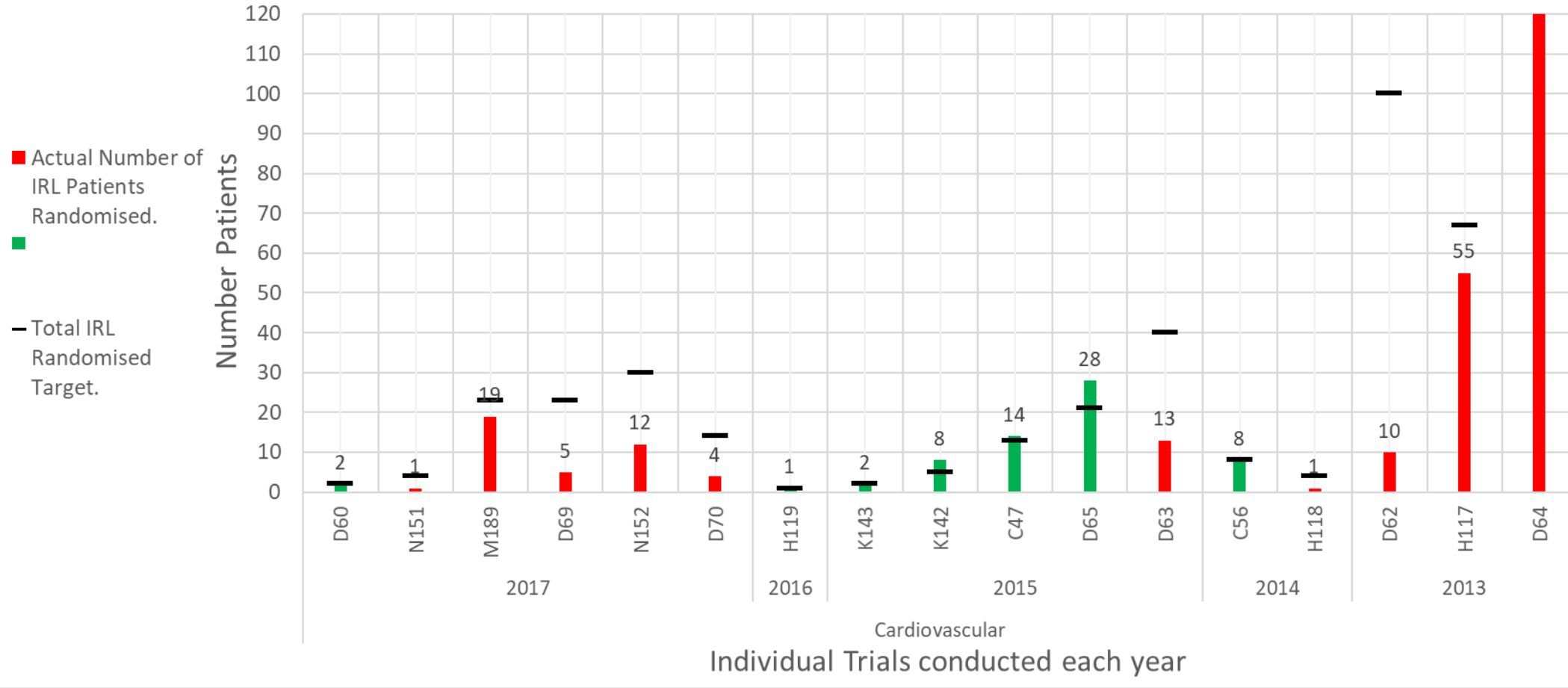


24 out of 45 (53%) Trials Hit Recruitment Target



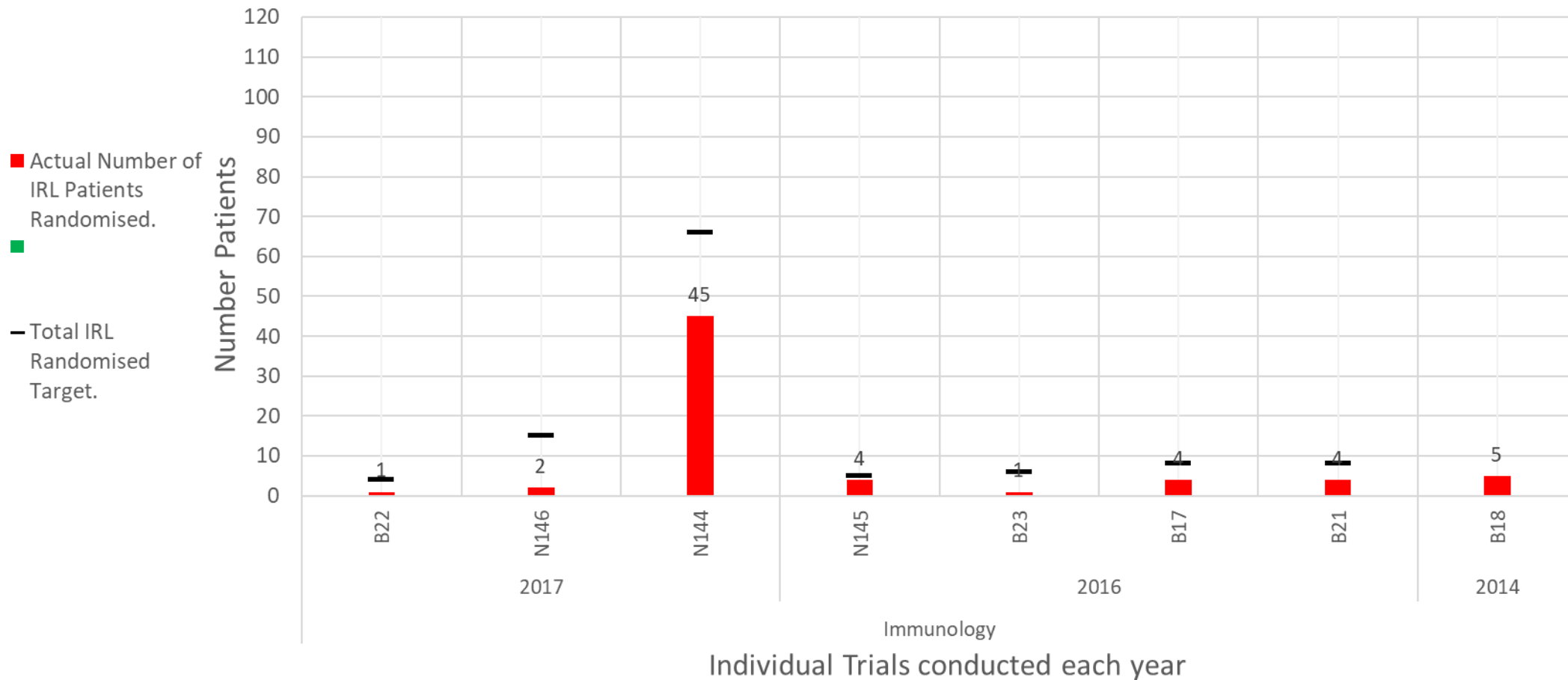
7 out of 17 (41%) Trials Hit Recruitment Target

Actual Number Patients Randomised vs Target Set



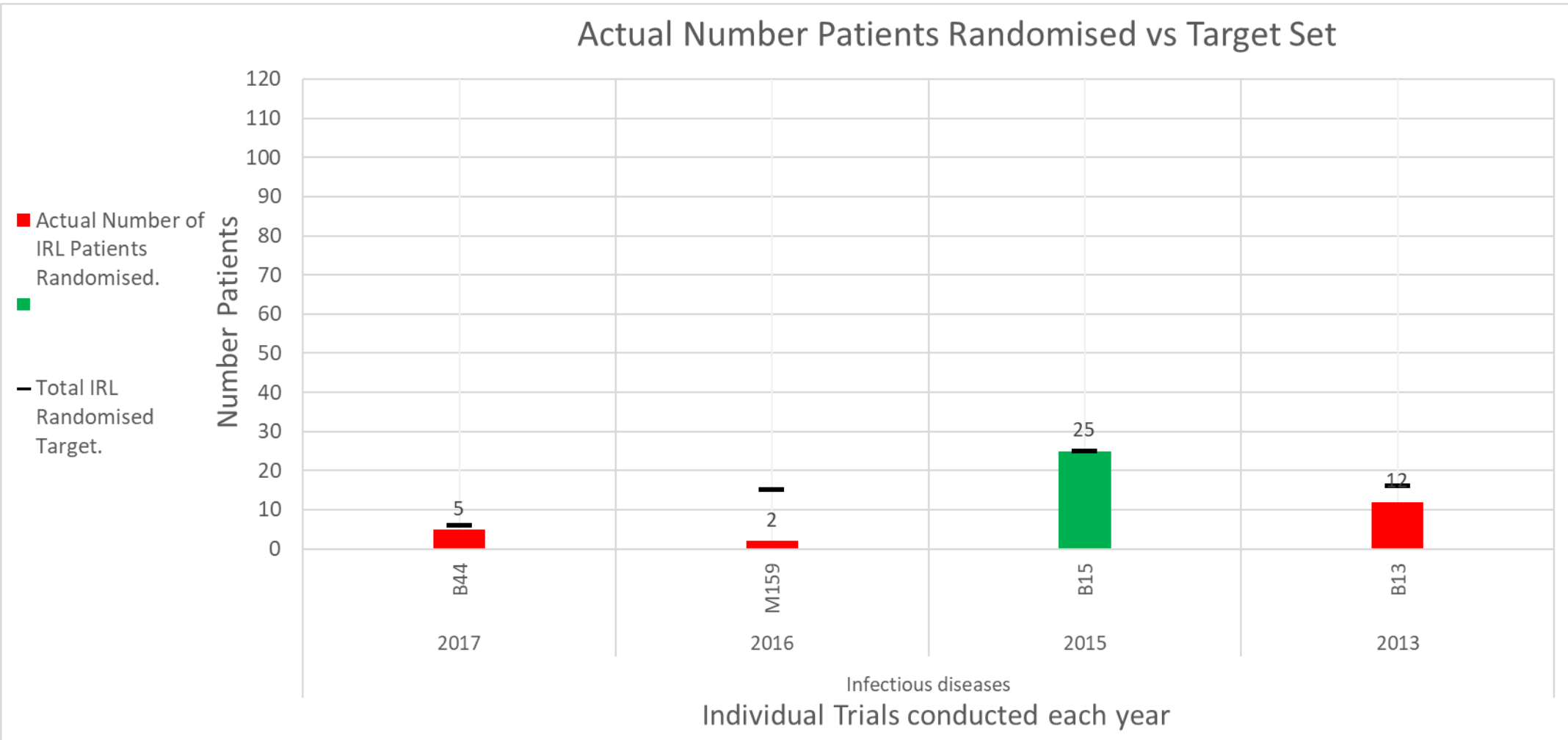
0 Trials (0%) Hit Recruitment Target

Actual Number Patients Randomised vs Target Set

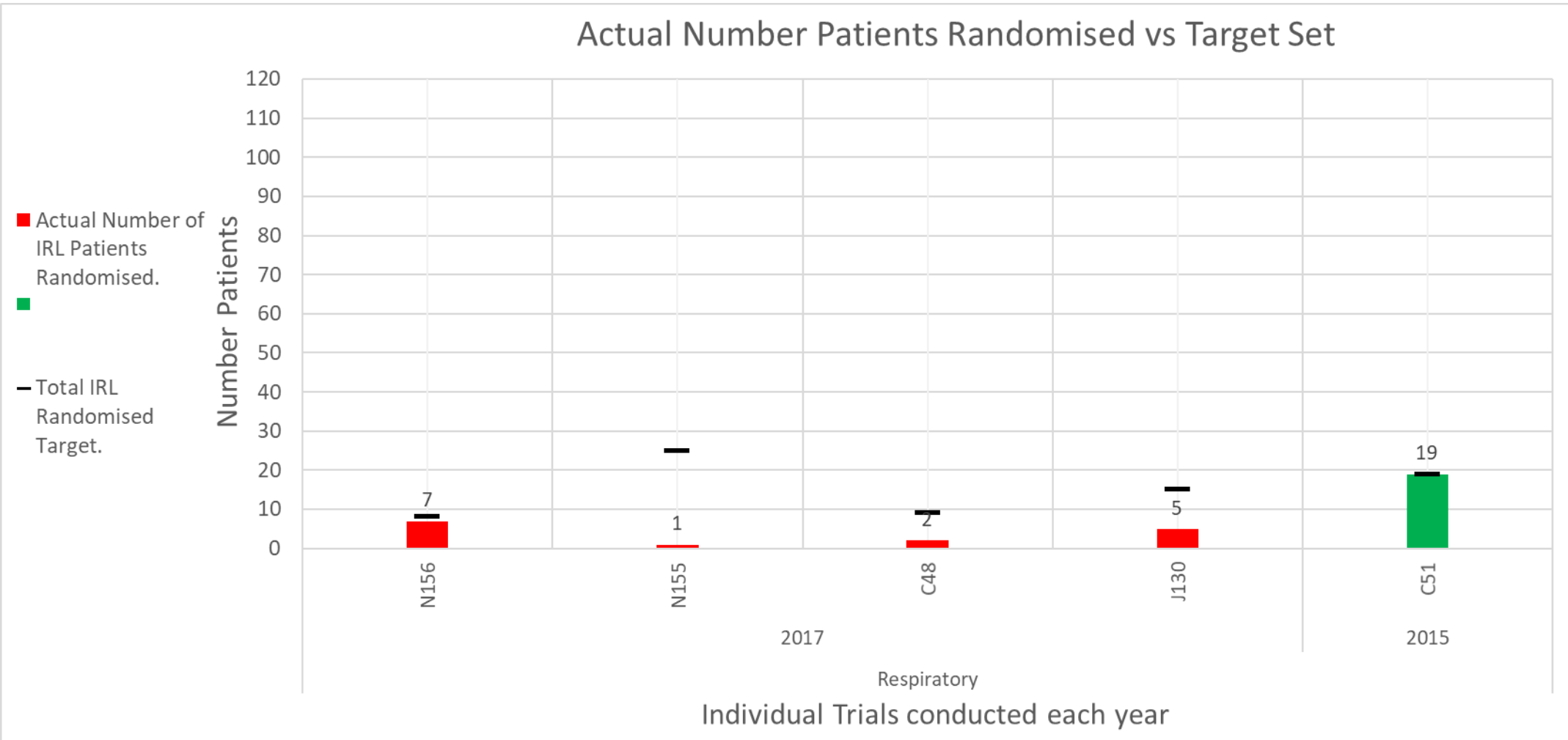


Infectious Diseases

1 in 4 (25%) Hit Recruitment Target



Respiratory 1 in 5 (20%) hit recruitment target



How Can We Attract More Studies?



How Can We Attract More Studies to Ireland?

- **Assess how start up activities can be more streamlined**
 - Adopting an Ireland-wide standard site contract (The Clinical Trial Agreement)
 - Protected research time for clinicians and hospital staff
 - Understand how can we can shorten the timeline from contract signature to site green light
- **Provide realistic targets that are achievable and be relied upon**
 - Meeting a lower target is better than partially meeting a higher target



How Can We Attract More Studies to Ireland?

- **Be consistent in our approach to clinical research across all institutions**
 - Empower a central body to drive performance and ensure accountability
 - Facilitate sharing best practice across sites
- **Require more data to show our competitiveness with other countries**
 - As an industry, we need to provide CT metrics to CREG to build on this initial baseline research
 - As an industry, we need to consistently produce good quality documents for Regulatory Bodies and Ethics Committees
 - Be more transparent around expectations - both from an industry and site perspective

Generate discussion to create partnerships to improve landscape.





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Thank You
Feedback and Questions



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