

# NATIONAL MUTUAL ACCEPTANCE METRICS

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# NMA – Key Performance Indicators

- 60 day benchmark for ethics review decision (with clock)
- Number of ethics reviews saved – measure of reduced duplication
- Note the following metrics are for clinical trials as non-clinical trial research has only 1 year of available data

# NMA - data methodology

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- A standard set of data fields is used to provide a minimal data set
- Key field criteria. Applications marked as:
  - NMA is mode of HREC review
  - Clinical trial
  - Multi-site
  - Time period in years from 2012 to 30 June 2016
  - Meeting date (ethics) for applications is within the designated time period/year
- The data set consists of dates (actions/decisions) and characteristics (e.g. drug/device/other, trial phase)

# NMA Benchmark and KPIs

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- **86%** clinical trials met the 60 day benchmark (n= 855, clock)
- **3165** ethics reviews were saved

## **Overall activity** (1 January 2012 to 30 June 2016)

- 1152 ethics reviews
- 4317 site assessments (SSAs)

**CTNs** – 687 applications

60% of applications

# Commercial and non-commercial clinical trials

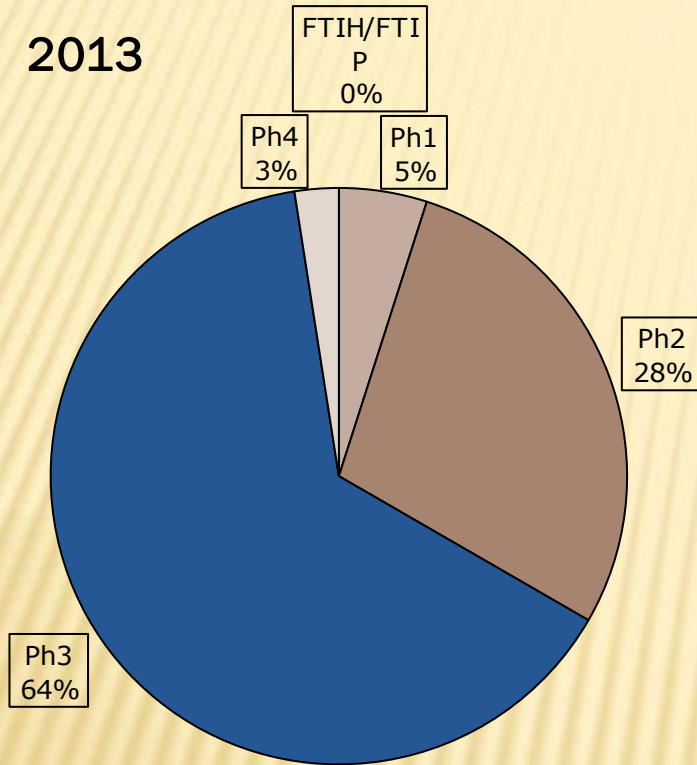
Comparison of per cent of trials meeting the 60 day benchmark for ethics (with clock)

Year	Commerically sponsored trials (%)	Non-commercial trials (%)
2011*	88	100
2012	85	92
2013	82	70
2014	84	87
2015	90	94
2016 (1/2 year)	92	93
Mean value/yr	87%	89%

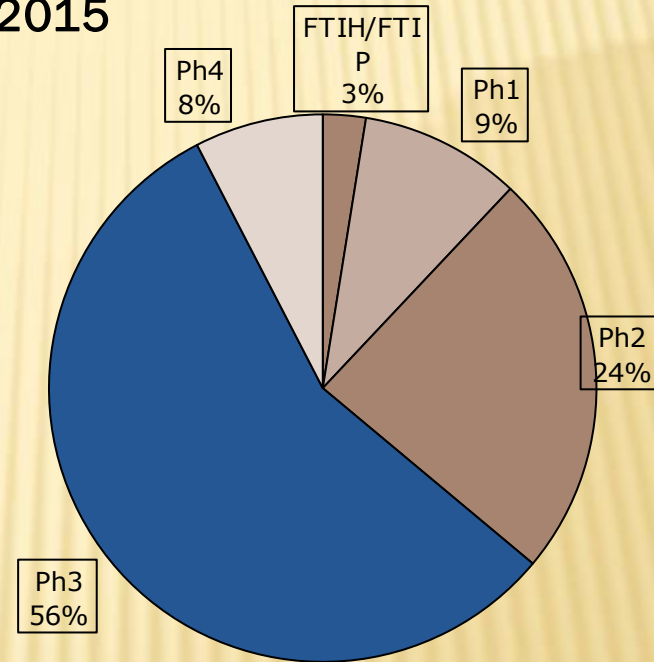
\* Small number

# Clinical trials by phase

2013



2015

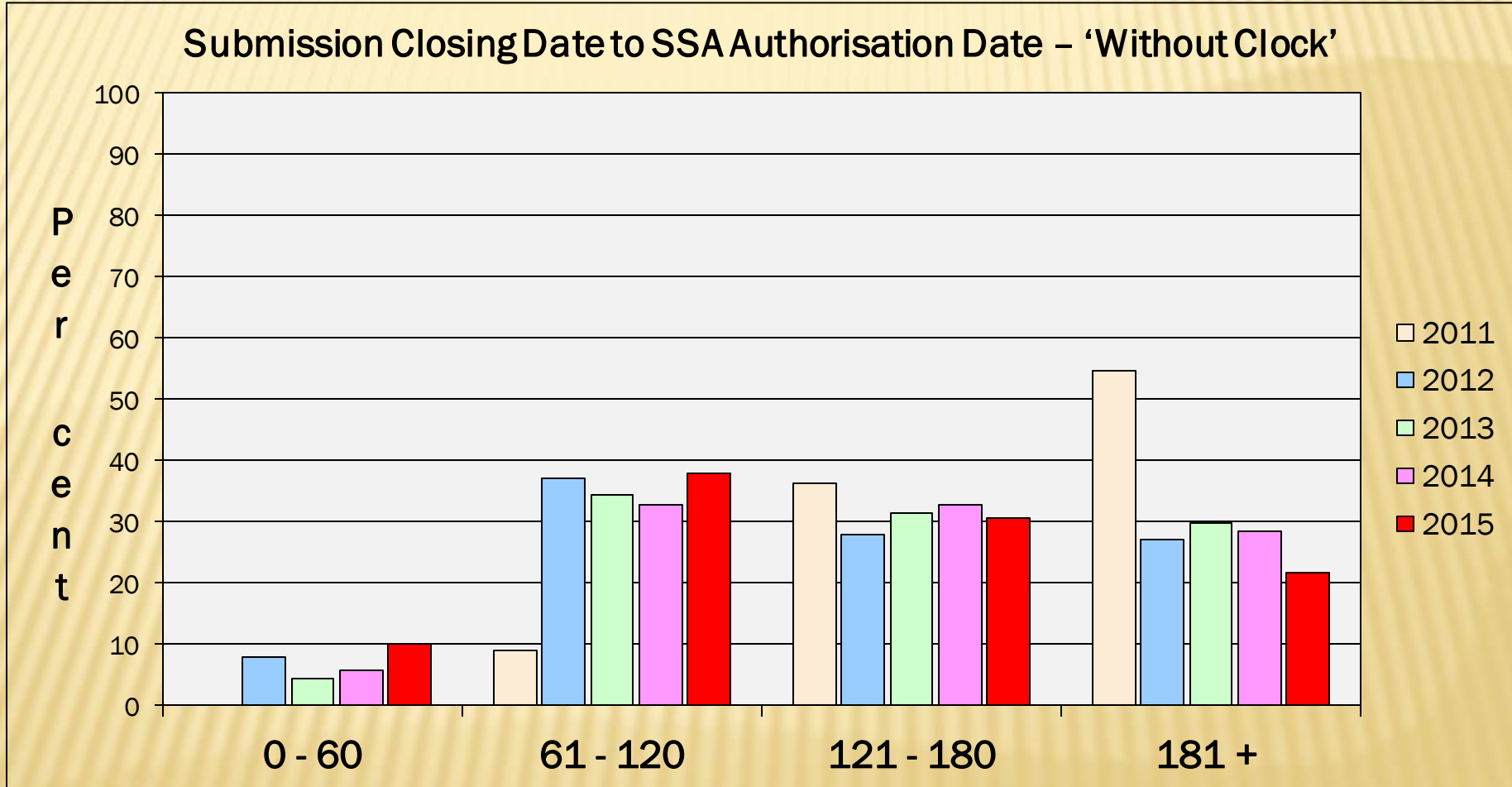


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## Regulatory process (Ethics and SSA) - Without clock

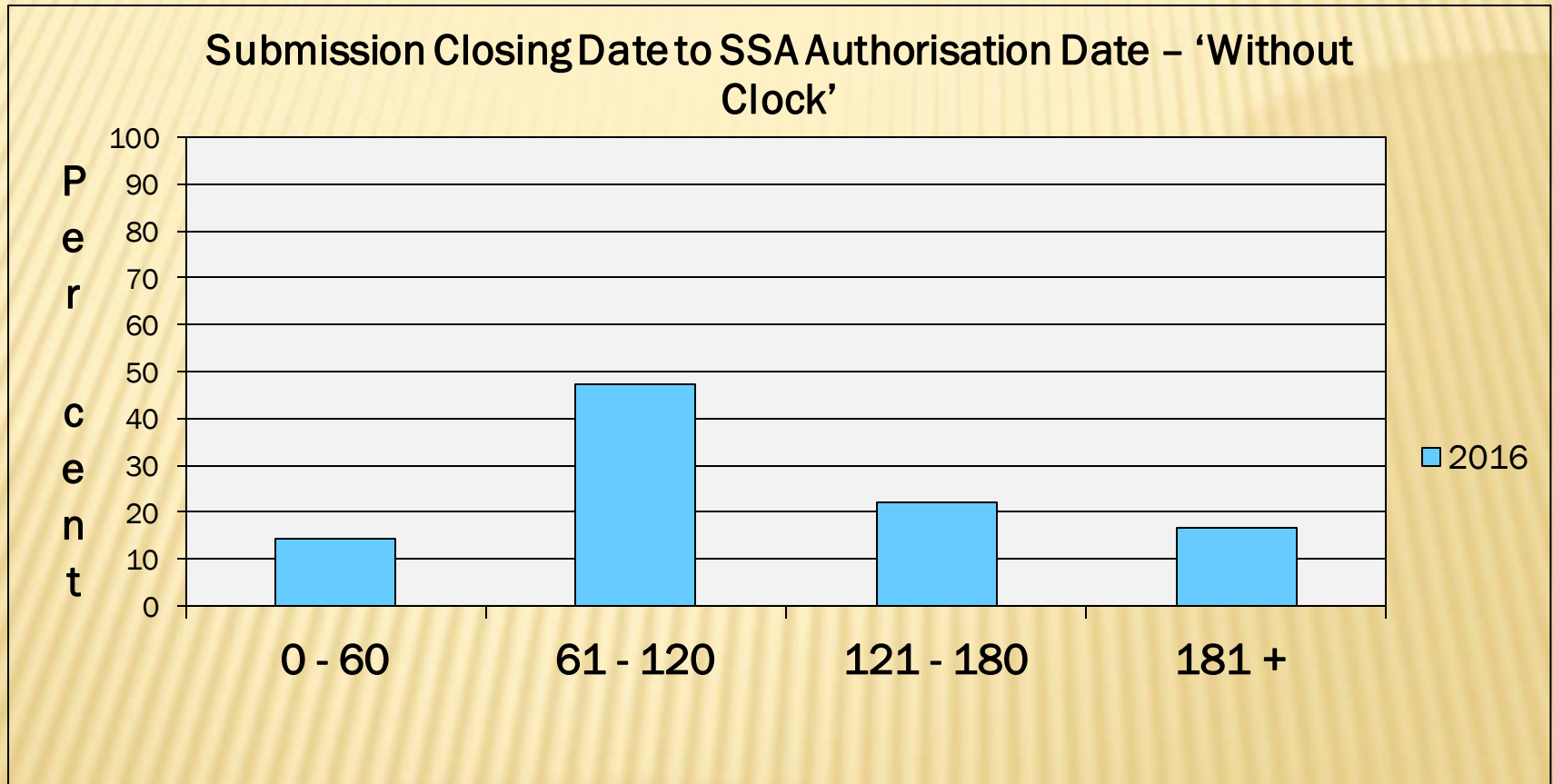
- This is a measure of timeliness for the entire process both ethics approval and SSA authorisation.
- It is the time for potential trial commencement of site preparation – start-up meetings, site-initiation visits etc.

# Timeliness: Regulatory process (Ethics and SSA) Without clock





# Regulatory process (Ethics and SSA) – 2016 (1/2 year) Without clock



## Summary - Regulatory process (Ethics and SSA- without clock)

	Percent of applications completed					
Time (days)	2011	2012	2013	2014	2015	2016 (1/2 yr)
0-60	0	8	4	6	10	14
61-120	9	37	34	33	38	47
Summary (days)						
0-120	9	45	38	39	48	61

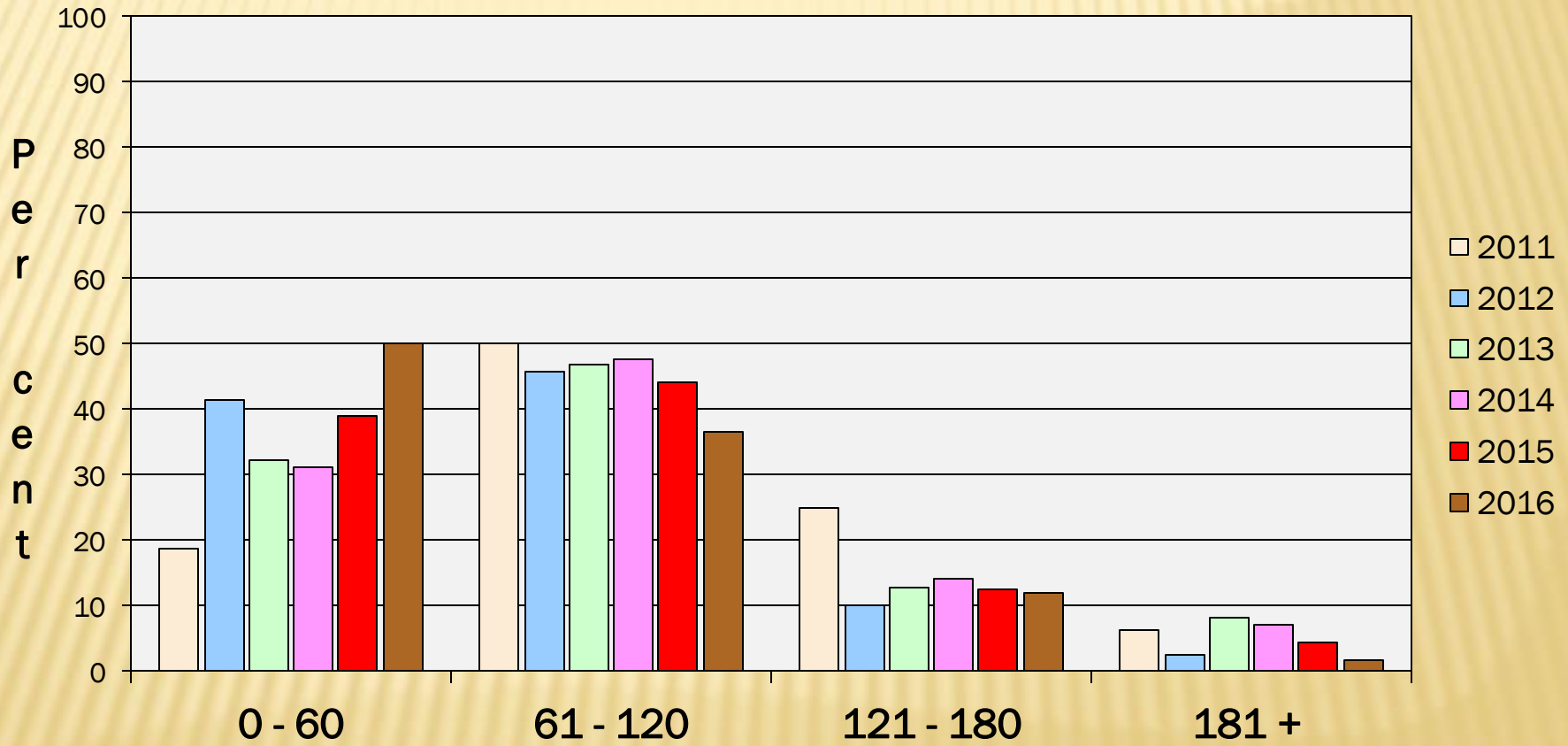
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## Timeliness for an Ethics review decision - without clock

- This is the total time taken to review and approve an ethics application
- A measure of the ethics and administration plus time to respond to the HREC requiring further information from the investigator/sponsor

# Timeliness: Ethics review decision Without clock

## Submission Closing Date to HREC Approval Date



# Ethics review decision - with clock-

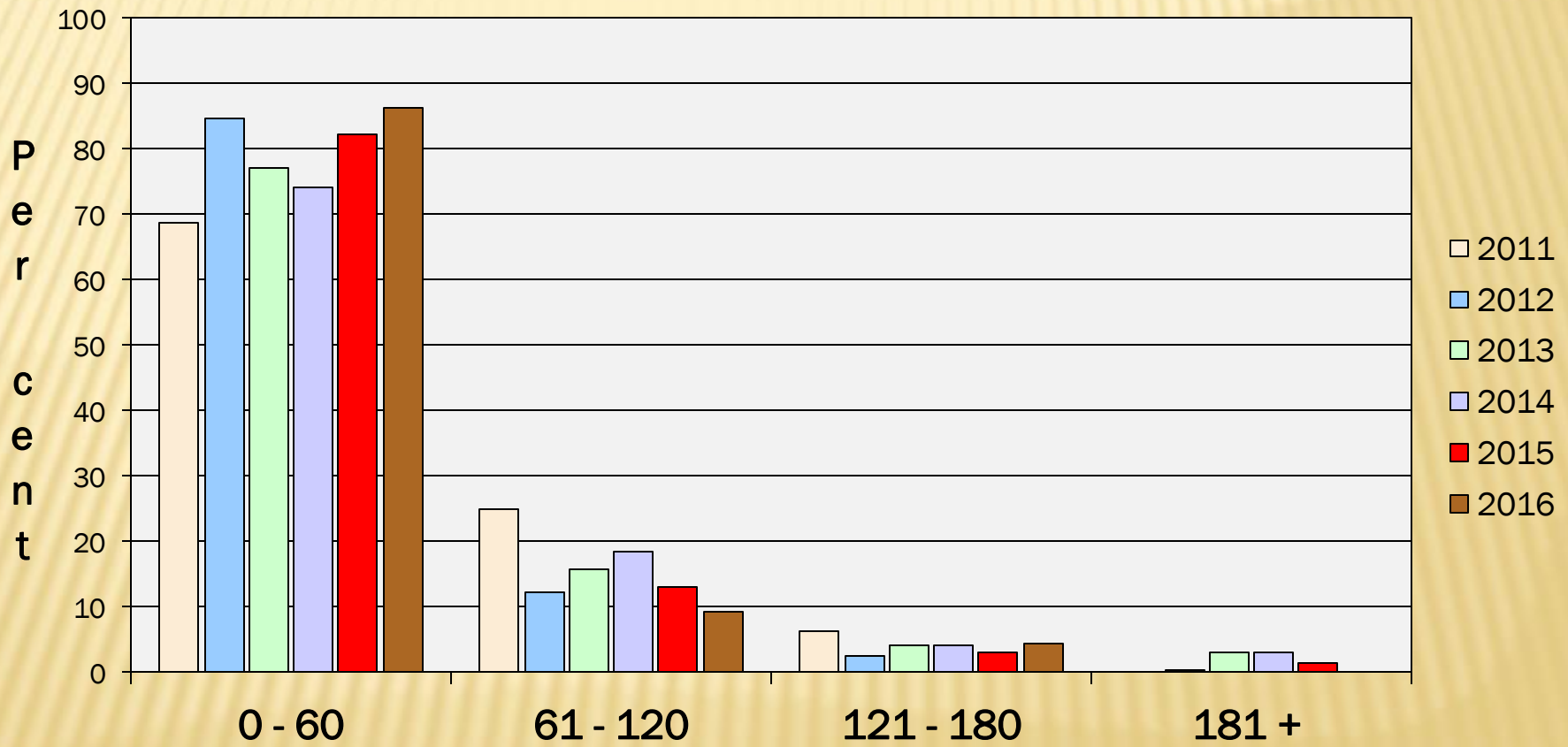
Timeliness for an Ethics review decision

- This is the time taken to review and approve an ethics application
- A measure of the ethics and administration time only

# Timeliness: Ethics review decision

## With clock- a measure of ethics & administration time only

Submission Closing Date to HREC Approval Date



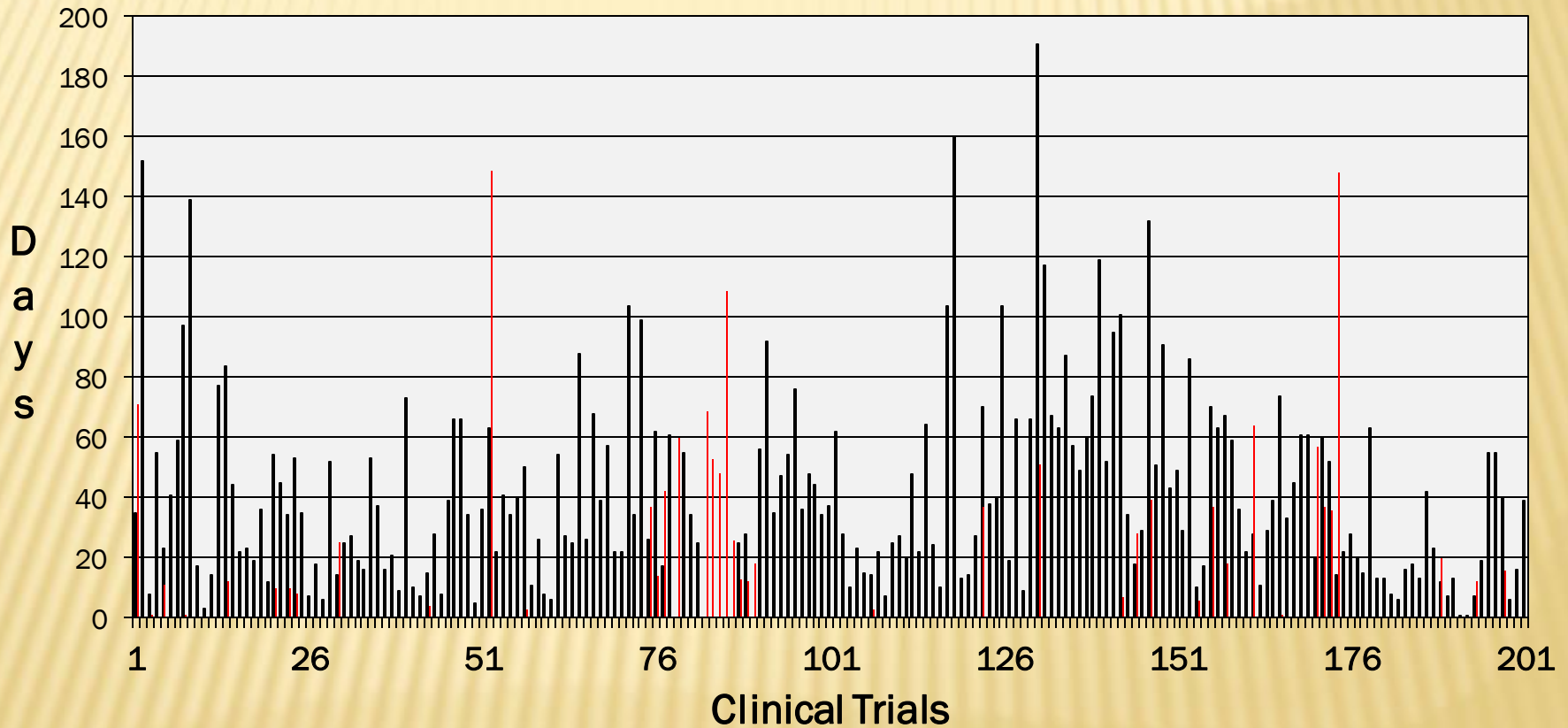
# Summary – Ethics review timeliness (without clock)

	Percent of ethics applications completed					
Time (days)	2011	2012	2013	2014	2015	2016 (1/2 yr)
0-60	19	42	32	31	39	50
61-120	50	46	47	48	44	36
Summary (days)						
0-120	69	88	79	79	83	86

# Delay analysis

## Ethics review – response to further information time

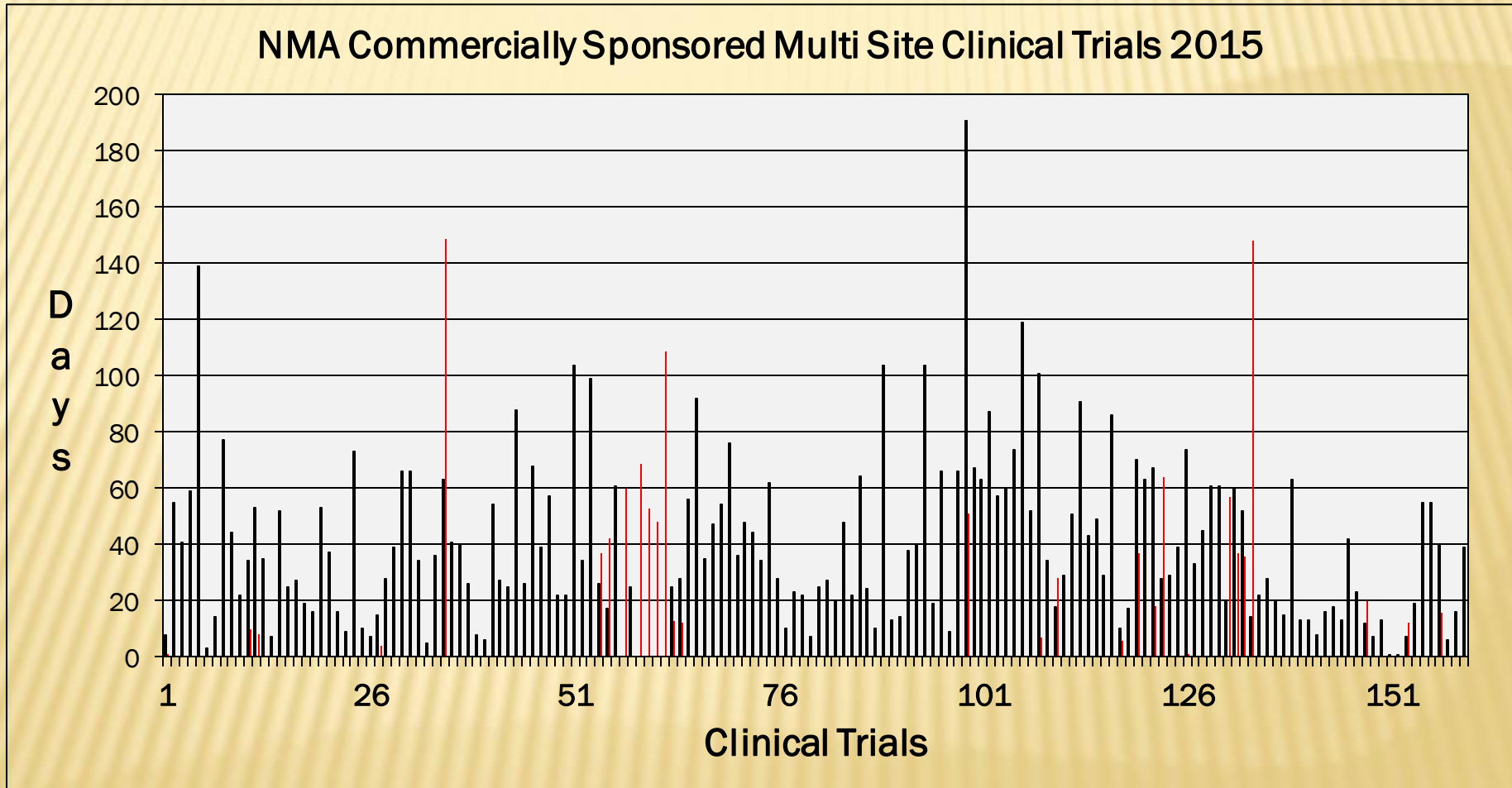
NMA Multi Site Clinical Trials 2015





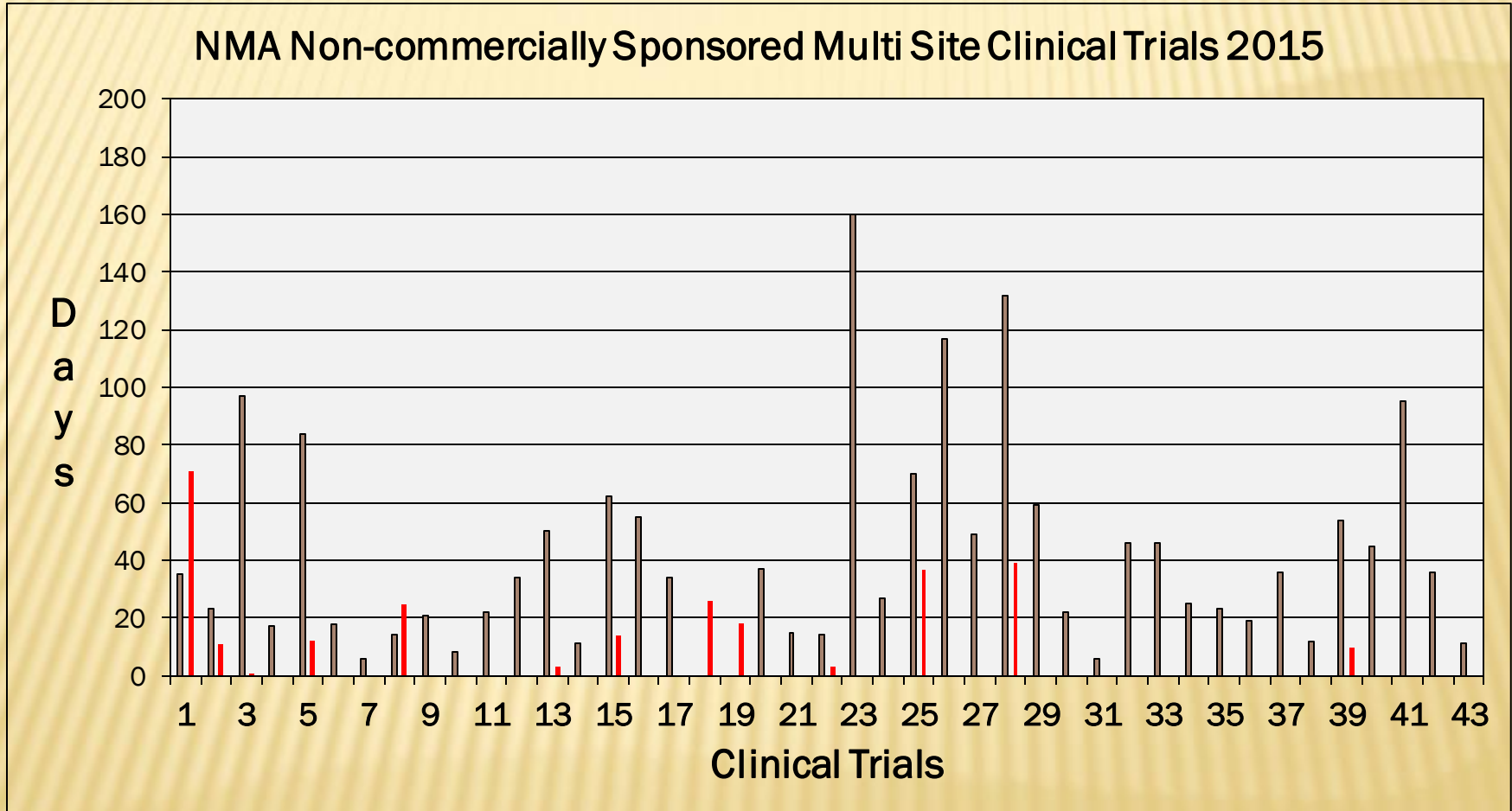
# Delay analysis

## Ethics review – response to further information time



# Delay analysis

## Ethics review – response to further information time



# Delay analysis

## Ethics review – request for further information

Time taken to respond to ethics “request for further information”

	Mean response time (days)	SD
All trials – first response	42	33
All trials – second response	34	35
Commercially sponsored – first response	42	33
Commercially sponsored – second response	36	39
Non-commercially sponsored – first response	41	35
Non-commercially sponsored – second response	19	19

# SSA Authorisation

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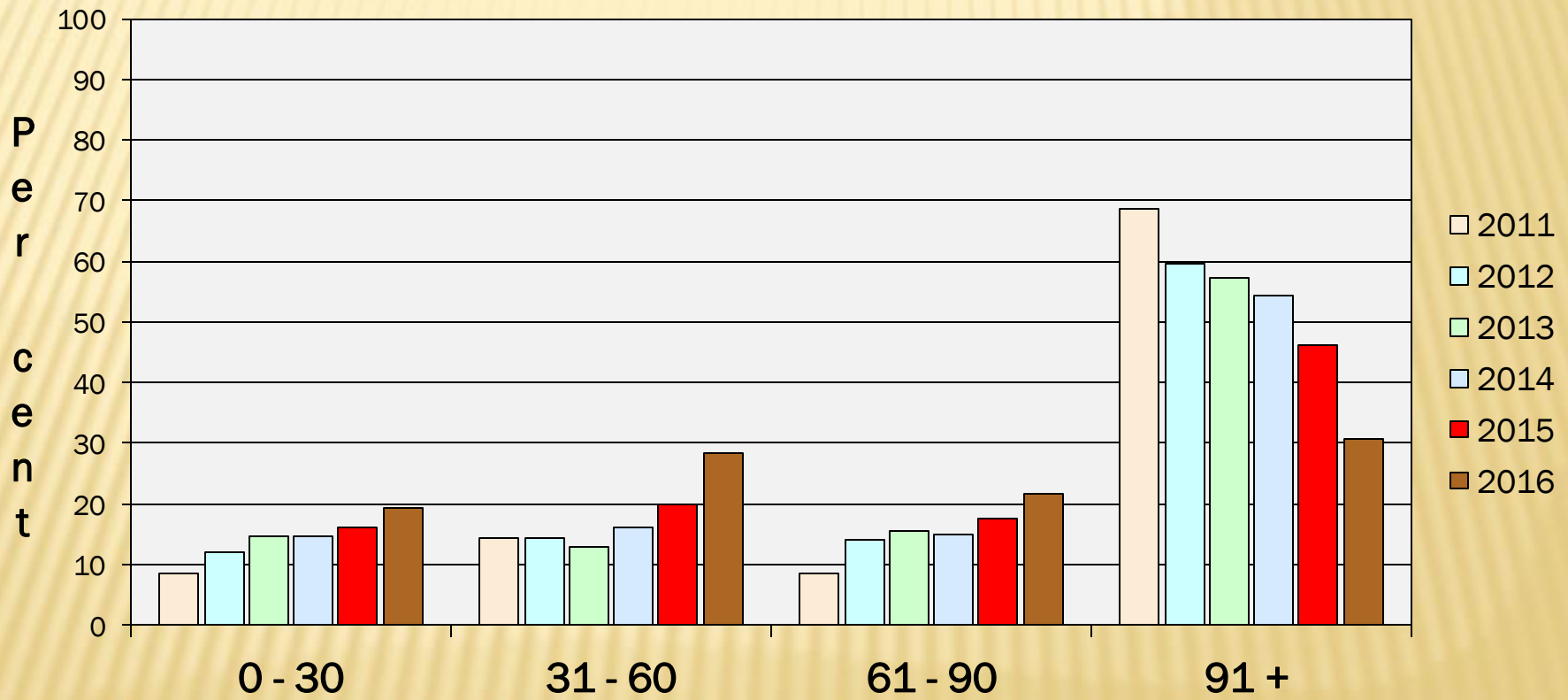
SSA Authorisation can be measured from 2 different starting points:

1. **HREC approval date** – this is the time when the process can be completed as HREC approval is final (measures the processes as a continuum)
2. **Validation date SSA** – a variable start time and no relation to the date of the HREC approval

All SSA timeliness is measured without clock (very varied use of the clock for SSAs)

# Timeliness: SSA Authorisation completion without clock

Time for SSA Authorisation:  
HREC Approval Date to SSA Authorisation Date – ‘Without Clock’



# Summary: time for completion of SSA authorisation - from Ethics approval date (without clock)

	Percent of SSAs completed					
Time (days)	2011	2012	2013	2014	2015	2016 (1/2 yr)
0-30	9	12	15	15	16	19
31-60	14	14	13	16	20	28
Summary (days)						
0-60	23	26	28	31	36	47

# Delay analysis

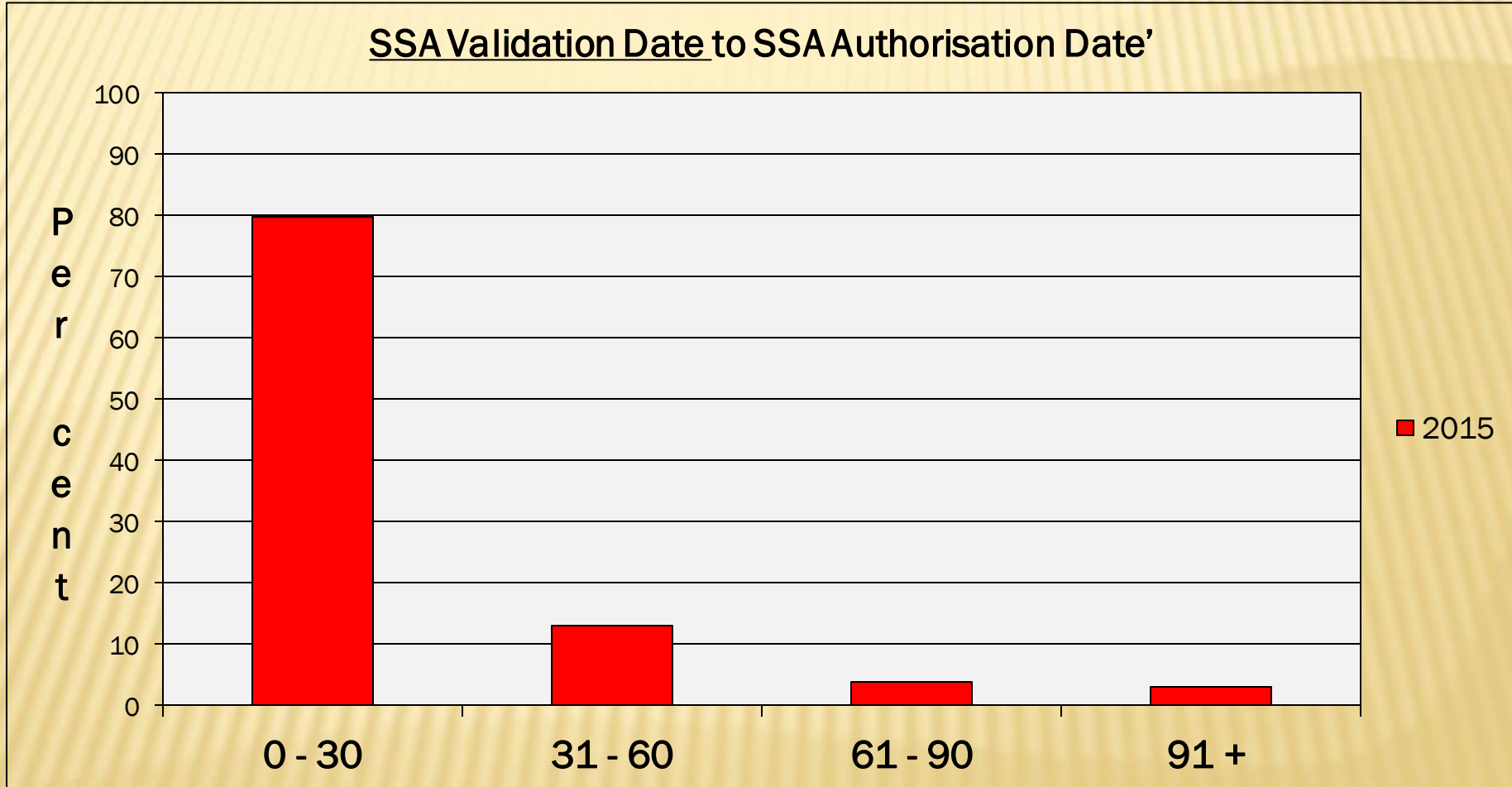
## Starting site specific assessment

Validation of SSA in relation to the HREC approval date  
(n=958 in 2015)

SSAs validated	Number SSAs	% SSAs
Before HREC approval date	60	6
After HREC approval date	898	94

# Timeliness: SSA Validation to Authorisation without clock

SSA Validation Date to SSA Authorisation Date'





# Key delays

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Ethics review – request for further information

- Response times from 20-40+ days
- Does not depend on whether commercially sponsored or non-commercially sponsored

What is a reasonable timeline for responding to a  
‘request for further information’?

- Reasons for the delay?

# Key delays

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## Site assessment process – a significant delay

- The total time for ethics and SSA is lengthy, only 10% of trials in 60 days and 48-61% in 120 days (2015/2016)
- From HREC approval date SSA is completed in 30 days for 16-19% of trials and 36-47% in 60 days

## Why?

- Not a parallel process – 6% of SSAs validated on/before HREC approval date

## Reasons

- Do **RGOs** require SSAs to be ‘complete’ before submission & validation – after HREC approval letter and final consent form/s, leading to prolonged budget negotiations?
- Do **investigators & sponsors** wait for HREC approval before activating SSAs?

SSA administration - 80% of SSAs are completed in 30 days