Research Ethics and Governance Metrics Project Biannual Report for 2016



17/03/2016

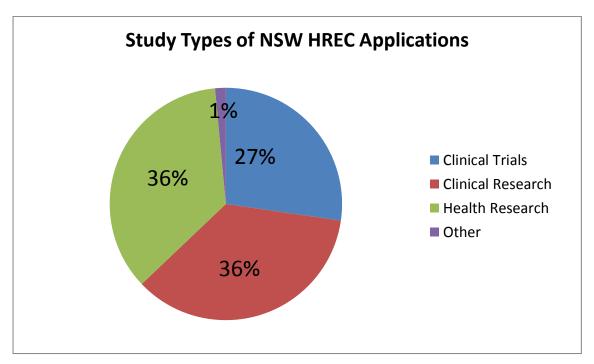
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METRIC 3: NSW HREC Submission Closing Date to NSW HREC Approval

Key Data: Human Research Ethics Application Review Timelines in NSW (with/without clock)

| | | With Clock | | | Without Clock | | | |
|------------------------|-------|------------|--------|--------|---------------|--------|--------|--|
| | Total | Mean | Median | Range | Mean | Median | Range | |
| Clinical Trials | 128 | 49 | 47 | 12-180 | 94 | 85 | 29-274 | |
| Non Clinical Trials | 341 | 46 | 41 | 0-264 | 94 | 71 | 0-423 | |
| TOTAL | 469 | 46 | 42 | 0-264 | 87 | 76 | 0-423 | |



Summary Notes:

- 75% of the Clinical Trials approved less than 60 days by NSW HRECs between 01/07/2016-31/12/2016.
- According to Australian National Aggregate Statistics report (2014-2015), 82% of the commercial clinical trials are reviewed under 60 days.
- In 6 months period, RPAH approved the highest number of clinical trials (37 clinical trials).
- RPAH's Clinical Trial review performance is the lowest in the state (30%).

Performance of NSW Human Research Ethics Committees (HRECs):

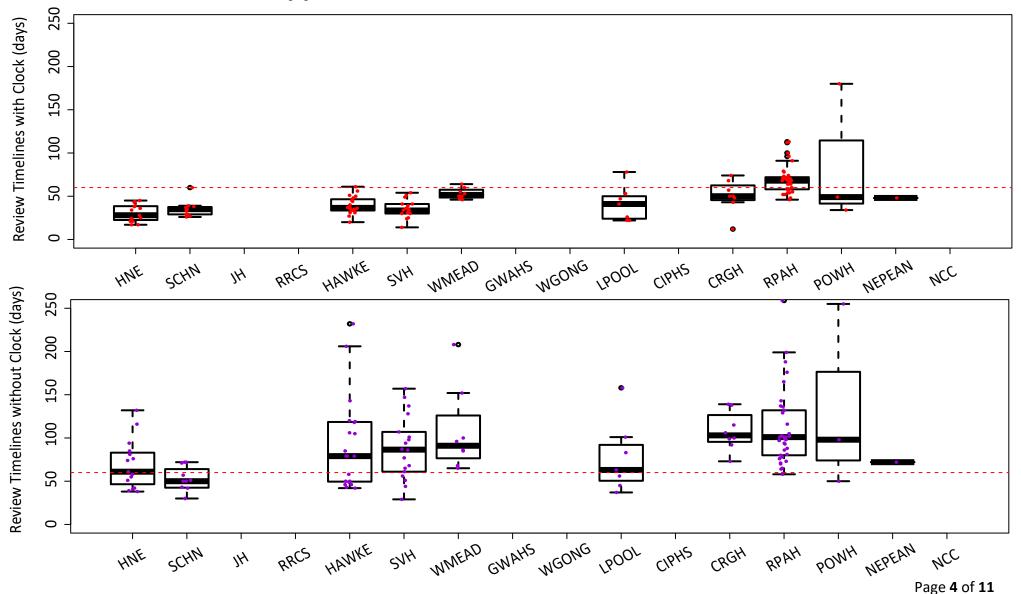
All studies (excluding LNR) approved in NSW between 01/07/2016 and 31/12/2016.

| AURED committees | Total # of applications | Reviewed under 60 days | % | Total # of Clinical Trials | Reviewed under 60 days | % | Total # of Non- Clinical Trials | Reviewed under 60 days | % |
|------------------|-------------------------|---------------------------|-----|-------------------------------|---------------------------|-----|------------------------------------|---------------------------|-----|
| HNE | 63 | 63 | 100 | 15 | 15 | 100 | 48 | 48 | 100 |
| SCHN | 28 | 28 | 100 | 11 | 11 | 100 | 17 | 17 | 100 |
| JH | 5 | 5 | 100 | N/A | | | 5 | 5 | 100 |
| RRCS | 1 | 1 | 100 | N /A | | | 1 | 1 | 100 |
| HAWKE | 45 | 44 | 98 | 20 | 19 | 95 | 25 | 25 | 100 |
| SVH | 37 | 36 | 97 | 18 | 18 | 100 | 19 | 18 | 95 |
| WMEAD | 35 | 32 | 91 | 8 | 7 | 88 | 27 | 25 | 93 |
| GWAHS | 11 | 10 | 91 | N/A | | | 11 | 10 | 91 |
| WGONG | 9 | 8 | 89 | N/A | | | 9 | 8 | 89 |
| LPOOL | 38 | 33 | 87 | 7 | 6 | 86 | 31 | 27 | 87 |
| CIPHS | 19 | 13 | 68 | N/A | | | 19 | 13 | 68 |
| CRGH | 26 | 17 | 65 | 8 | 6 | 75 | 18 | 11 | 61 |
| RPAH | 105 | 64 | 61 | 37 | 11 | 30 | 68 | 53 | 78 |
| POWH | 38 | 20 | 53 | 3 | 2 | 67 | 35 | 18 | 51 |
| NEPEAN | 8 | 4 | 50 | 1 | 1 | 100 | 7 | 3 | 43 |
| NCC | 1 | 0 | 0 | N/A | | | 1 | 0 | 0 |
| TOTAL | 469 | 378 | 81 | 128 | 96 | 75 | 341 | 282 | 83 |

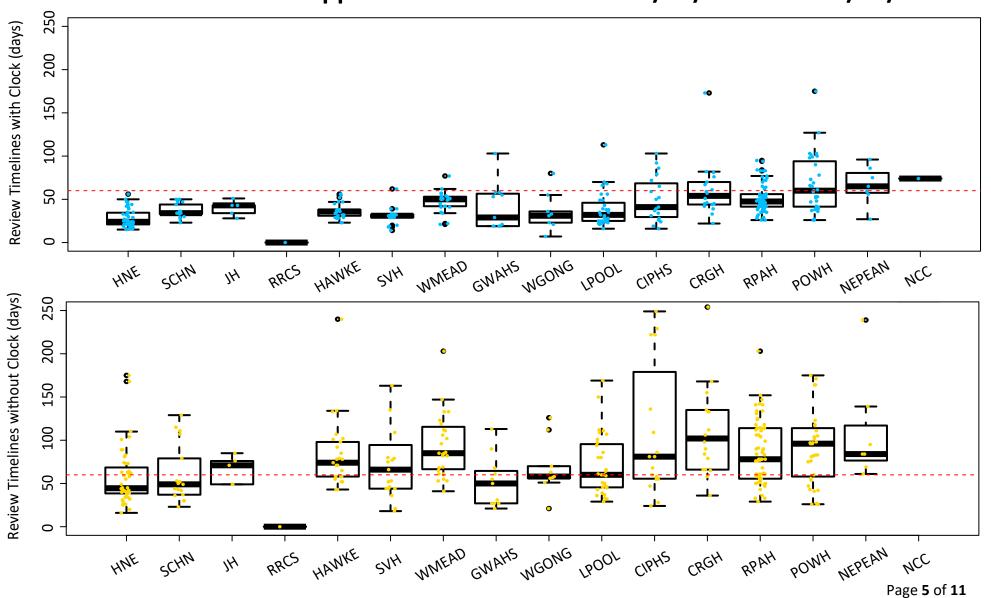
Performance Threshold:

| Highly Performing | Underperforming | Not Performing |
|-------------------|-----------------|----------------|
| 90% or better | ≥ 75% and < 90% | <75% |

Clinical Trials Approved in NSW between 01/07/2016 and 31/12/2016



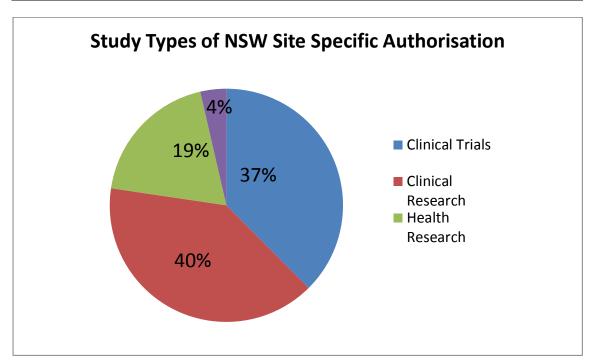
Non-Clinical Trials Approved in NSW between 01/07/2016 and 31/12/2016



METRIC 4: Date Valid SSA Application Received by the RGO to Site Authorisation

Key Data: Site Authorisation Timelines in NSW (with/without clock)

| | | 1 | With Cloc | k | Without Clock | | | |
|---------------------|-------|------|-----------|-------|---------------|--------|--------|--|
| | Total | Mean | Median | Range | Mean | Median | Range | |
| Clinical Trials | 333 | 20 | 11 | 0-374 | 49 | 26 | 0-745 | |
| Non Clinical Trials | 554 | 20 | 11 | 0-218 | 60 | 31 | 0-1118 | |
| TOTAL | 887 | 46 | 42 | 0-374 | 56 | 29 | 0-1118 | |



Summary Notes:

- 81% of the Clinical Trials approved less than 30 days by NSW HRECs between 01/07/2016-31/12/2016.
- According to Australian National Aggregate Statistics report (2014-2015), 93% of the commercial clinical trials are authorised under 60 days without the clock. This report excluded the multi-jurisdictional studies.
- In 6 months period, LPOOL authorised the 3rd highest number of studies (105 studies, 38 of these were clinical trials).
- LPOOL Site Specific Authorisation performance is the lowest in the state (16%). Based on our initial consultation with the site, they have experienced difficulties in staff allocation.

Performance of Site Specific Authorisation (SSAs):

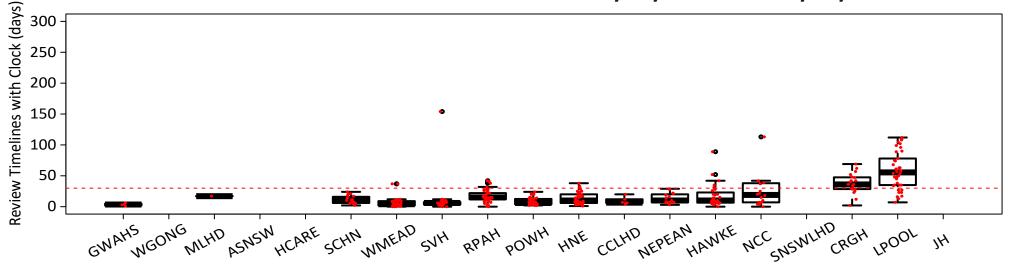
All studies (excluding LNR) authorised in NSW between 01/07/2016 and 31/12/2016.

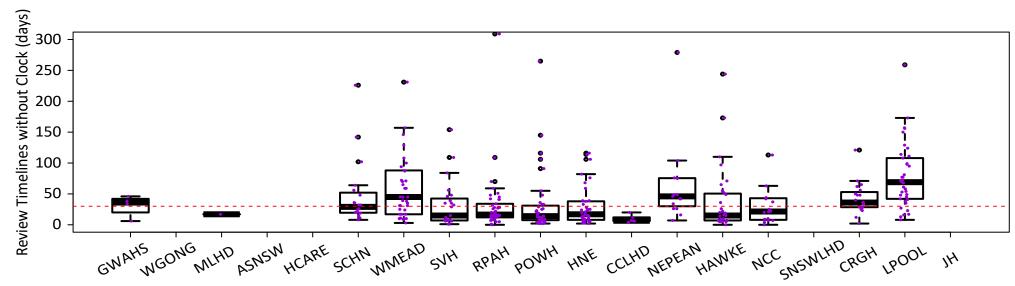
| AURED committees | Total # of applications | Reviewed under 30 days | % | Total # of Clinical Trials | Reviewed under 30 days | % | Total # of Non- Clinical Trials | Reviewed under 30 days | % |
|------------------|-------------------------|---------------------------|-----|-------------------------------|---------------------------|-----|------------------------------------|------------------------|-----|
| GWAHS | 17 | 17 | 100 | 4 | 4 | 100 | 13 | 13 | 100 |
| WGONG | 6 | 6 | 100 | N/A | | | 6 | 6 | 100 |
| MLHD | 5 | 5 | 100 | 1 | 1 | 100 | 4 | 4 | 100 |
| ASNSW | 1 | 1 | 100 | N/A | | | 1 | 1 | 100 |
| HCARE | 1 | 1 | 100 | N/A | | | 1 | 1 | 100 |
| SCHN | 60 | 58 | 97 | 20 | 20 | 100 | 40 | 38 | 95 |
| WMEAD | 116 | 112 | 97 | 42 | 40 | 95 | 74 | 72 | 97 |
| SVH | 52 | 50 | 96 | 23 | 22 | 96 | 29 | 28 | 97 |
| RPAH | 118 | 113 | 96 | 42 | 38 | 90 | 76 | 75 | 99 |
| POWH | 92 | 88 | 96 | 39 | 39 | 100 | 53 | 49 | 92 |
| HNE | 104 | 98 | 94 | 37 | 34 | 92 | 67 | 64 | 96 |
| CCLHD | 12 | 11 | 92 | 6 | 6 | 100 | 6 | 5 | 83 |
| NEPEAN | 39 | 35 | 90 | 15 | 15 | 100 | 24 | 20 | 83 |
| HAWKE | 70 | 58 | 83 | 31 | 25 | 81 | 39 | 33 | 85 |
| NCC | 28 | 19 | 68 | 16 | 11 | 69 | 12 | 8 | 67 |
| SNSWLHD | 3 | 2 | 67 | N/A | | | 3 | 2 | 67 |
| CRGH | 57 | 32 | 56 | 19 | 7 | 37 | 38 | 25 | 66 |
| LPOOL | 105 | 17 | 16 | 38 | 8 | 21 | 67 | 9 | 13 |
| JH | 1 | 0 | 0 | N/A | | | 1 | 0 | 0 |
| TOTAL | 887 | 723 | 82 | 333 | 270 | 81 | 554 | 453 | 82 |

Performance Threshold:

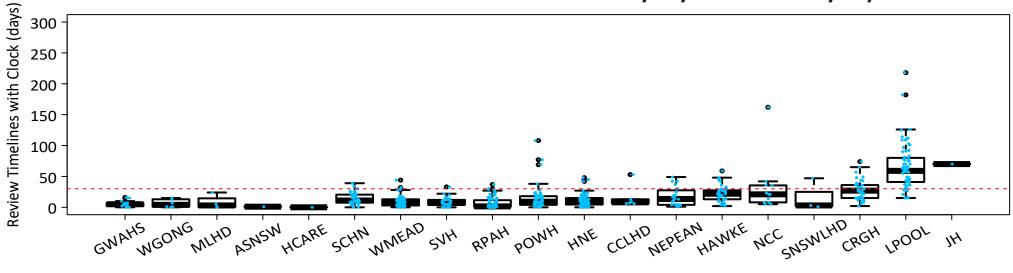
| Highly Performing | Underperforming | Not Performing |
|-------------------|-----------------|----------------|
| 90% or better | ≥ 75% and < 90% | <75% |

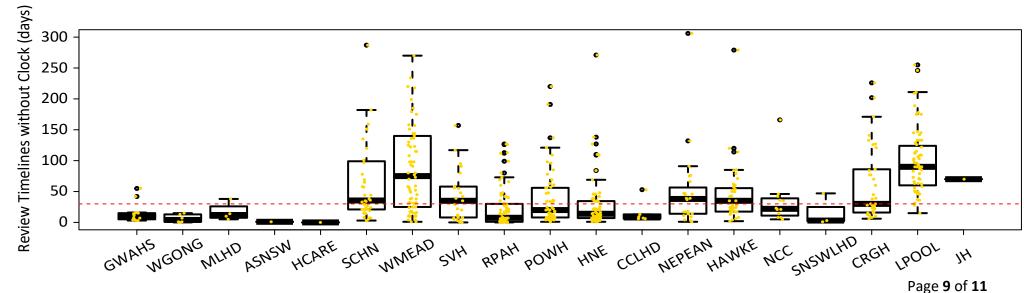
Clinical Trials Authorised in NSW between 01/07/2016 and 31/12/2016





Non-Clinical Trials Authorised in NSW between 01/07/2016 and 31/12/2016





Committee Names and Abbreviations:

| HREC | AU RED Code |
|--|-------------|
| NSW Population & Health Services Research Ethics Committee | CIPHS |
| SLHN Human Research Ethics Committee | CRGH |
| Northern Sydney LHD HREC | HAWKE |
| Hunter New England Human Research Ethics Committee | HNE |
| South Western Sydney LHD HREC | LPOOL |
| Nepean Blue Mountains LHD HREC | NEPEAN |
| South Eastern Sydney LHD HREC (Northern Sector) | POWH |
| Sydney Local Health District Ethics Review Committee (RPA Zone) | RPAH |
| Sydney Children's Hospitals Network Human Research Ethics Committee | SCHN |
| St Vincent's Hospital HREC | SVH |
| Joint University of Wollongong and Illawarra Shoalhaven Local Health District Health and Medical Human Research Ethics Committee | WGONG |
| Western Sydney Local Health District Human Research Ethics Committee | WMEAD |
| SSA | AU RED Code |
| Ambulance Service of NSW | ASNSW |
| Central Coast LHD | CCLHD |
| The Cancer Council NSW Ethics Committee | CCNSW |
| NSW Population & Health Services Research Ethics Committee | CIPHS |
| SLHN Human Research Ethics Committee | CRGH |
| Greater Western Human Research Ethics Committee | GWAHS |
| Northern Sydney LHD HREC | HAWKE |
| Hammond Care | HCARE |
| Hunter New England Human Research Ethics Committee | HNE |
| Justice Health & Forensic Mental Health Network Human Research Ethics Committee | JH |
| South Western Sydney LHD HREC | LPOOL |
| Murrumbidgee RGO | MLHD |
| North Coast NSW Human Research Ethics Committee | NCC |
| Nepean Blue Mountains LHD HREC | NEPEAN |
| South Eastern Sydney LHD HREC (Northern Sector) | POWH |
| Sydney Local Health District Ethics Review Committee (RPA Zone) | RPAH |
| Royal Rehabilitation Centre Sydney HREC | RRCS |
| Sydney Children's Hospitals Network Human Research Ethics Committee | SCHN |
| Southern NSW RGO | SNSWLHD |
| St Vincent's Hospital HREC | SVH |
| Joint University of Wollongong and Illawarra Shoalhaven Local Health District Health and Medical Human Research Ethics Committee | WGONG |
| Western Sydney Local Health District Human Research Ethics Committee | WMEAD |

Note: Research Ethics and Governance Reform grant was not provided to the institutions shown in grey (CCNSW, HCARE and RRCS)

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