

OHMR Research Ethics and Governance Metrics Program



Metrics Activity Report for NSW PHOs

Reporting Period: Quarter 4 2021

(01/10/2021 – 31/12/2021)

NSW Office for Health and Medical Research



Health



Executive Summary

This report includes strategic and site level performance and compliance metrics that are collected by the Office for Health and Medical Research (OHMR) from NSW Public Health Organisations (PHOs) on studies authorised between 1st of Oct 2021 and 31st of Dec 2021. The performance of NSW PHOs on health and medical research are reported four times a year, each covering a 3-month period.

Overall Performance Environment

REGIS is the online platform used to manage ethics and governance applications for all NSW Public Health Organisations. OHMR has undertaken data validation activities with LHD Research Office staff to accurately represent research ethics and governance performance on this platform. These rolling validation activities may result in data reported here to differ from previous reports.

Update to Metrics Program

As reported previously, OHMR implemented the following changes to the Research Key Performance Indicators (KPIs) for inclusion in the Chief Executives' Services Agreement:

- Change benchmark to measure Total Time rather than time spent with LHD Research Office alone
- Number of Greater than Low Risk projects (GLR) processed within application total time
 - 90 days for ethics, 60 days for governance
 - Threshold changes
 - >75% = Performing
 - 55%-75% = Underperforming
 - <55% = Not performing



Ethics Review Timelines of Human Research in NSW PHOs

KPI21-03: Ethics Application Approvals - By the Human Research Ethics Committee (HREC) within 90 calendar days

NSW State Benchmark: The benchmark for the 2021/22 financial year onwards is for reviewing human research studies by NSW PHO HRECs within 90 calendar days

Definition:

The proportion of Ethics applications (excluding LNR) approved by the HREC within 90 calendar days, approved within the reporting period.

Context:

The measure will no longer account for clock stops in accordance with the NHMRC Certification Handbook. Instead, the end-to-end time will be measured. Where a valid application is received, the clock starts on the submission closing date for the HREC meeting at which an application will be reviewed. The clock is stopped when the HREC formally notifies the applicant of the final decision.

Desired Outcome:

Ensuring timely processing of ethics approvals for research and clinical trials supports better health outcomes for the people of NSW and maintaining competitiveness through access to the latest treatments from clinical trials.

Selection Criteria Summary:

Scope	Human Research Ethics Applications
Frequency	Quarterly
Inclusions	<ul style="list-style-type: none"> Study Type = All Application Type = Greater than low risk Approval Type = Approved/ Approved with conditions within the reporting period
Exclusions	<ul style="list-style-type: none"> Application Type = Low and negligible risk Approval Type = Not within the reporting period Migrated studies

Total Time:

Total time is defined as the measurement of the total, unadjusted time from the Submission Closing Date of the first meeting the application is assigned to, to when the final decision notification email is sent.

Summary:

Ethics review performance of NSW HRECs according to the **<90-day benchmark** for studies approved between 01/10/2021 and 31/12/2021 (Quarter 4 2021) are shown in **Table 1**. In Quarter 4 2021, **269 studies** (greater than low risk pathway) were approved by an HREC with an average review time (total time) of **62 days**. Of these 269 studies, **100 (37%)** were classified as clinical trials (**Table 2**). Further breakdown of clinical trial approvals by sponsor type is provided in **Table 3 (by NSW PHOs)** and **Table 4 (by quarter)**. Historical performance of NSW PHOs against the old and new benchmarks for the review and approval of human research ethics applications is presented in **Table 5**.

Table 1. The 90 calendar days benchmark for approval of human research ethics applications (greater than low risk) between 01/10/2021 – 31/12/2021

Ethics Approval (Q4 2021)							
All greater than low risk applications							
NSW PHOs	Total Number of Applications	Total Time 90 Day Benchmark			Total Time Breakdown (Calendar days)		Count Request for Information
		Count <90 Day Benchmark	% <90 Day Total Time Benchmark	Average Total Time (Days)	Average Research Office Time	Average Researcher Time	
BLLBRRY	26	23	88%	43	26	17	2.8
CINSW	15	13	87%	108	33	75	1.5
HNELHD	37	32	86%	63	23	40	2.0
ISLHD	6	4	67%	92	45	47	1.5
JHFMHN	1	0	0%	134	76	58	2.0
NBMLHD	8	6	75%	105	42	63	1.1
NNSWLHD	2	2	100%	70	36	34	1.5
NSLHD	7	7	100%	38	15	23	1.1
SCHN	17	11	65%	74	38	36	1.8
SESLHD	17	15	88%	69	31	38	2.1
SLHD-CCD	12	11	92%	56	24	32	2.0
SLHD-RPA	41	39	95%	42	15	27	1.4
SVHN	33	33	100%	41	25	16	1.3
SWSLHD	22	16	73%	82	32	51	2.0
WNSWLHD	4	4	100%	42	32	11	1.3
WSLHD	21	18	86%	67	39	28	1.8
TOTAL	269	234	87%	62	28	34	1.8

Table 2. The 90 calendar days benchmark for the approval of clinical trials (greater than low risk) between 01/10/2021 and 31/12/2021.

Ethics Approval (Q4 2021) Clinical Trials							
NSW PHOs	Total Number of Applications	Total Time 90 Day Benchmark			Total Time Breakdown (Calendar days)		Count Request for Information
		Count <90 Day Benchmark	% <90 Day Total Time Benchmark	Average Total Time (Days)	Average Research Office Time	Average Researcher Time	
BLLBRRY	26	23	88%	43	26	17	2.8
CINSW	0	0	-	-	-	-	-
HNELHD	8	8	100%	53	24	29	2.3
ISLHD	1	1	100%	65	40	25	1.0
JHFMHN	0	0	-	-	-	-	-
NBMLHD	0	0	-	-	-	-	-
NNSWLHD	0	0	-	-	-	-	-
NSLHD	4	4	100%	38	14	24	1.3
SCHN	10	5	50%	87	41	46	2.1
SESLHD	3	2	67%	139	63	76	1.7
SLHD-CCD	6	5	83%	62	29	33	1.7
SLHD-RPA	13	13	100%	43	14	29	1.6
SVHN	11	11	100%	47	29	18	1.5
SWSLHD	4	2	50%	87	37	50	3.3
WNSWLHD	0	0	-	-	-	-	-
WSLHD	14	13	93%	62	39	23	1.6
TOTAL	100	87	87%	57	29	28	2.1

Table 3. Breakdown of NSW PHO performances in **clinical trial approvals** (greater than low risk) between 01/10/2021 and 31/12/2021 **by sponsor type**

NSW PHOs	Collaborative group			Commercial entity			Investigator-initiated		
	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)
BLLBRRY	-	-	-	25	26	44	1	6	15
CINSW	-	-	-	-	-	-	-	-	-
HNELHD	-	-	-	1	25	64	7	24	51
ISLHD	-	-	-	-	-	-	1	40	65
NSLHD	1	22	43	3	11	36	-	-	-
SCHN	1	27	31	7	46	103	2	31	58
SESLHD	1	30	48	-	-	-	2	80	184
SLHD-CCD	1	17	21	3	32	79	2	29	56
SLHD-RPA	1	12	47	4	17	51	8	14	39
SVHN	2	20	31	5	31	54	4	32	47
SWSLHD	-	-	-	3	43	107	1	17	28
WSLHD	1	48	74	10	38	63	3	37	54
Total	8	25	41	61	31	60	31	28	55

Table 4. Quarterly **clinical trial approvals** (greater than low risk) between 01/01/2021 and 31/12/2021, **by sponsor type**

Sponsor Type	Q1 2021			Q2 2021			Q3 2021			Q4 2021		
	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)
Collaborative Group	2	26	52	7	22	152	10	30	87	8	25	41
Commercial Entity	40	29	93	24	24	62	41	24	57	61	31	60
Investigator Initiated	29	38	103	49	24	80	40	24	63	31	28	55
Total	71	33	96	80	24	81	91	25	63	100	29	57

Table 5. Historical performance of NSW PHOs against the old and new benchmarks for the review and approval of human research ethics applications (greater than low risk) between 01/01/2021 and 31/12/2021.

LHD	Q1				Q2				Q3				Q4			
	45 Day Benchmark (with clock)		90 Day Benchmark (without clock)		45 Day Benchmark (with clock)		90 Day Benchmark (without clock)		45 Day Benchmark (with clock)		90 Day Benchmark (without clock)		45 Day Benchmark (with clock)		90 Day Benchmark (without clock)	
	% 45 Day Benchmark	Average Metric Time (Days)	% 90 Day Total Time Benchmark	Average Total Time (Days)	% 45 Day Benchmark	Average Metric Time (Days)	% 90 Day Total Time Benchmark	Average Total Time (Days)	% 45 Day Benchmark	Average Metric Time (Days)	% 90 Day Total Time Benchmark	Average Total Time (Days)	% 45 Day Benchmark	Average Metric Time (Days)	% 90 Day Total Time Benchmark	Average Total Time (Days)
BLLBRRY	81%	28	63%	77	100%	21	85%	50	95%	25	90%	55	96%	26	88%	43
CINSW	100%	30	44%	86	100%	29	81%	72	100%	31	81%	84	87%	33	87%	108
HNELHD	78%	35	48%	96	89%	27	75%	75	94%	28	83%	86	100%	23	86%	63
ISLHD	38%	73	38%	127	0%	46	50%	178	67%	44	83%	72	67%	45	67%	92
JHFMHN	0%	303	0%	291	33%	46	33%	122	100%	38	0%	602	0%	76	0%	134
NBMLHD	100%	33	80%	82	90%	35	90%	69	78%	38	89%	70	50%	42	75%	105
NNSWLHD	60%	34	40%	91	100%	25	100%	66	33%	57	67%	232	100%	36	100%	70
NSLHD	94%	31	69%	84	95%	22	73%	82	100%	25	80%	56	100%	15	100%	38
SCHN	100%	28	48%	97	92%	29	75%	93	100%	26	93%	58	59%	38	65%	74
SESLHD	50%	44	40%	104	58%	50	42%	142	92%	25	100%	38	88%	31	88%	69
SLHD-CCD	100%	17	64%	89	100%	23	56%	85	100%	26	47%	121	100%	24	92%	56
SLHD-RPA	97%	16	48%	95	100%	14	70%	79	98%	15	82%	68	100%	15	95%	42
SVHN	73%	40	32%	116	79%	33	79%	77	95%	26	84%	64	94%	25	100%	41
SWSLHD	81%	35	42%	107	100%	25	76%	88	100%	19	91%	63	86%	32	73%	82
WNSWLHD	33%	51	67%	90	33%	56	67%	105	91%	32	100%	11	100%	32	100%	42
WSLHD	100%	27	82%	67	100%	26	79%	67	94%	32	78%	61	71%	39	86%	67
TOTAL	83%	29	51%	78	91%	26	73%	82	95%	26	83%	72	89%	28	87%	62



Site-specific Assessment (SSA) Authorisation Timelines of Human Research Projects in NSW PHOs

KPI21-04: Research Governance Application Authorisations – SSA Authorisations within 60 calendar days

NSW State Benchmark: The benchmark for the 2021/22 financial year onwards for authorisation of SSA applications is 60 calendar days

Definition:

The proportion of site-specific assessment (SSA) applications (excluding lower to negligible risk) authorised by the Research Governance Office (RGO) within 60 calendar days, authorised within the reporting period.

Context:

The measure will no longer account for clock stops in accordance with the National Health and Medical Research Council Certification Handbook. Instead, the end-to-end time will be measured. The SSA application received date is the date the RGO or designee receives an SSA application from a researcher regardless of whether it is complete and/or deemed valid. The clock is stopped when the final SSA decision letter is provided to the site principal investigator.

Desired Outcome:

Ensuring timely processing of site approvals for research and clinical trials supports better health outcomes for the people of NSW and maintaining competitiveness through access to the latest treatments from clinical trials.

Selection Criteria Summary:

Scope	Site-specific assessment (SSA) applications
Frequency	Quarterly
Inclusions	<ul style="list-style-type: none"> • Study Type = All • Application Type = Greater than low risk • Approval Type = “Authorised” or “authorised with conditions” within the reporting period
Exclusions	<ul style="list-style-type: none"> • Application Type = Low and negligible risk • Approval Type = Not within the reporting period • Migrated studies

Total Time:

Total time is the measurement of the total, unadjusted time from the Submission Date to when the final decision notification email is sent granting approval.

Summary for Metric 4:

SSA review performance of NSW PHOs according to the **<60-day benchmark** for studies authorised between 01/10/2021 and 31/12/2021 (Quarter 4 2021) are shown in **Table 6**. In Quarter 4 2021, **547** studies (greater than low risk pathway) were authorised in NSW PHOs with an average review time (total time) of **56 days**. Of these 547 studies, **275** (50%) were classified as clinical trials (**Table 7**). Further breakdown of clinical trial SSA authorisations by sponsor type is provided in **Table 8 (by NSW PHOs)** and **Table 9 (by quarter)**. Historical performance of NSW PHOs against the old and new benchmarks for the review and authorisation of governance applications is presented in **Table 10**.

Table 6: The 60 calendar days benchmark for authorisation of governance applications (greater than low risk) between 01/10/2021 – 31/12/2021.

NSW PHOs	SSA Approvals (Q4 2021)							
	All greater than low risk applications							
	Total Number of Applications	60 Day Benchmark (without clock)			Total Time Breakdown (calendar days)			
Count of <60 Day Benchmark		% <60 Day Total Time Benchmark	Average Total Time (Days)	Average Research Office Time	Average Head of Dept Time	Average Chief Exec Time	Average Researcher Time	
ASNSW	0	0	-	-	-	-	-	-
CALVARY	13	13	100%	13	8	2	1	1
CCLHD	20	15	75%	63	19	16	0	28
FWLHD	0	0	-	-	-	-	-	-
HNELHD	57	43	75%	54	10	15	1	28
ISLHD	17	17	100%	11	2	4	1	4
JHFMHN	0	0	-	-	-	-	-	-
MLHD	4	4	100%	21	12	2	1	7
MNCLHD	8	6	75%	56	16	8	9	23
NBMLHD	23	16	70%	71	16	28	5	22
NNSWLHD	6	6	100%	25	12	0	3	10
NSLHD	38	24	63%	59	6	13	0	39
NSWHPTH	5	2	40%	122	6	15	0	101
SCHN	36	14	39%	85	18	19	0	47
SESLHD	35	26	74%	81	10	45	0	26
SLHD-CCD	29	23	79%	59	7	38	0	14
SLHD-RPA	60	49	82%	38	4	12	5	17
SNSWLHD	0	0	-	-	-	-	-	-
SVHN	46	31	67%	79	13	26	3	37
SWSLHD	60	40	67%	58	11	14	0	33
WNSWLHD	15	14	93%	23	3	3	0	16
WSLHD	75	61	81%	43	8	12	2	21
TOTAL	547	404	74%	56	10	18	2	27

Table 7: The 60 calendar days benchmark for the authorisation of clinical trials (greater than low risk) between 01/10/2021 and 31/12/2021.

NSW PHOs	SSA Approvals (Q4 2021) Clinical Trials							
	Total Number of Applications	60 Day Benchmark (without clock)			Total Time Breakdown (calendar days)			
		Count of <60 Day Benchmark	% <60 Day Total Time Benchmark	Average Total Time (Days)	Average Research Office Time	Average Head of Dept Time	Average Chief Exec Time	Average Researcher Time
ASNSW	0	0	-	-	-	-	-	-
CALVARY	10	10	100%	11	8	2	1	1
CCLHD	10	6	60%	88	24	22	0	42
FWLHD	0	0	-	-	-	-	-	-
HNELHD	21	19	90%	32	11	5	1	15
ISLHD	5	5	100%	15	1	2	0	12
JHFMHN	0	0	-	-	-	-	-	-
MLHD	0	0	-	-	-	-	-	-
MNCLHD	4	3	75%	61	16	10	14	21
NBMLHD	9	6	67%	73	24	12	6	31
NNSWLHD	0	0	-	-	-	-	-	-
NSLHD	20	14	70%	47	8	8	0	31
NSWHPH	1	1	100%	23	5	0	0	18
SCHN	17	6	35%	86	17	20	0	48
SESLHD	15	12	80%	43	13	24	0	6
SLHD-CCD	18	14	78%	43	10	19	0	14
SLHD-RPA	28	21	75%	42	4	16	7	14
SNSWLHD	0	0	-	-	-	-	-	-
SVHN	28	21	75%	65	10	35	0	21
SWSLHD	37	24	65%	61	11	13	0	36
WNSWLHD	4	4	100%	21	3	3	0	16
WSLHD	48	45	94%	34	7	11	2	14
TOTAL	275	211	77%	49	10	15	2	22

Table 8. NSW PHO performances in clinical trial authorisations (greater than low risk) between 01/10/2021 and 31/12/2021, by sponsor type

NSW PHOs	Collaborative group			Commercial entity			Investigator-initiated		
	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)
Calvary	1	5	6	8	6	11	1	19	19
CCLHD	5	25	73	3	3	18	2	55	231
HNELHD	6	14	59	8	12	16	7	7	28
ISLHD	3	1	18	2	2	11	-	-	-
MNCLHD	-	-	-	3	8	37	1	38	133
NBMLHD	3	27	72	4	14	41	2	39	138
NSLHD	7	12	49	7	5	27	6	6	69
NSWHPH	1	5	23	-	-	-	-	-	-
SCHN	6	23	97	7	14	64	4	16	108
SESLHD	8	12	41	6	15	44	1	2	50
SLHD-CCD	3	9	75	10	8	32	5	15	45
SLHD-RPA	3	7	17	15	4	25	10	5	74
SVHN	3	8	65	17	11	42	8	8	114
SWSLHD	12	12	100	17	11	43	8	10	42
WNSWLHD	3	3	27	-	-	-	1	2	2
WSLHD	7	7	36	28	8	24	13	7	54
Total	71	12	60	135	9	32	69	11	71

Table 9. Quarterly clinical trial authorisations (greater than low risk applications) approved between 01/01/2021 and 31/12/2021, by sponsor type

Sponsor Type	Q1 2021			Q2 2021			Q3 2021			Q4 2021		
	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)
Collaborative Group	32	14	91	43	9	75	48	9	38	71	12	60
Commercial Entity	114	10	45	112	9	39	100	10	30	135	9	32
Investigator Initiated	66	14	72	86	11	105	61	11	82	69	11	71
Total	212	12	61	241	10	69	209	10	47	275	10	49

Table 10. Historical performance of NSW PHOs against the old and new benchmarks for the review and authorisation of SSA applications (greater than low risk) between 01/01/2021 and 31/12/2021.

LHD	Q1				Q2				Q3				Q4			
	15 Day Benchmark (with clock)		60 Day Benchmark (without clock)		15 Day Benchmark (with clock)		60 Day Benchmark (without clock)		15 Day Benchmark (with clock)		60 Day Benchmark (without clock)		15 Day Benchmark (with clock)		60 Day Benchmark (without clock)	
	% 15 Day Benchmark	Average Metric Time (Days)	% 60 Day Total Time Benchmark	Average Total Time (Days)	% 15 Day Benchmark	Average Metric Time (Days)	% 60 Day Total Time Benchmark	Average Total Time (Days)	% 15 Day Benchmark	Average Metric Time (Days)	% 60 Day Total Time Benchmark	Average Total Time (Days)	% 15 Day Benchmark	Average Metric Time (Days)	% 60 Day Total Time Benchmark	Average Total Time (Days)
ASNSW	100%	0	0%	76	100%	6	100%	11	-	-	-	-	-	-	-	-
CALVARY	63%	15	94%	30	67%	15	100%	17	70%	11	90%	20	92%	8	100%	13
CCLHD	21%	29	43%	79	75%	18	67%	70	29%	25	57%	130	70%	19	75%	63
FWLHD	-	-	-	-	50%	10	100%	14	-	-	-	-	-	-	-	-
HNELHD	28%	29	64%	65	61%	14	79%	40	100%	5	85%	42	81%	10	75%	54
ISLHD	100%	6	54%	63	82%	8	71%	89	89%	5	89%	34	100%	2	100%	11
JHFMHN	33%	52	33%	114	100%	8	100%	19	-	-	-	-	-	-	-	-
MLHD	0%	45	0%	109	100%	6	100%	13	100%	6	100%	19	75%	12	100%	21
MNCLHD	33%	22	83%	46	56%	21	78%	71	67%	13	17%	177	75%	16	75%	56
NBMLHD	71%	13	47%	104	57%	15	43%	114	47%	21	53%	102	52%	16	70%	71
NNSWLHD	86%	7	57%	66	50%	12	100%	12	50%	24	100%	27	67%	12	100%	25
NSLHD	91%	8	50%	89	95%	6	62%	71	100%	6	69%	64	97%	6	63%	59
NSWHPTH	78%	13	11%	143	67%	13	17%	135	64%	13	55%	80	100%	6	40%	122
SCHN	89%	7	44%	74	81%	14	44%	105	77%	10	54%	68	58%	18	39%	85
SESLHD	91%	5	76%	44	90%	6	76%	45	84%	7	68%	57	77%	10	74%	81
SLHD-CCD	93%	5	86%	85	100%	6	62%	66	90%	9	65%	61	93%	7	79%	59
SLHD-RPA	81%	7	65%	70	78%	11	74%	51	82%	7	73%	49	93%	4	82%	38
SNSWLHD	-	-	-	-	0%	55	0%	108	43%	37	71%	50	-	-	-	-
SVHN	75%	12	50%	75	72%	13	72%	62	76%	10	70%	61	78%	13	67%	79
SWSLHD	94%	7	45%	105	98%	4	65%	87	98%	5	63%	103	77%	11	67%	58
WNSWLHD	100%	1	83%	19	88%	5	63%	117	100%	1	100%	10	100%	3	93%	23
WSLHD	95%	8	62%	70	91%	9	63%	76	93%	9	83%	62	92%	8	81%	43
TOTAL	80%	11	59%	75	83%	10	66%	71	85%	9	71%	65	83%	10	74%	56

A list of NSW PHOs names and abbreviations that review and/or authorise human research studies:

Human Research Ethics Committee/ Research Governance Office Names	Abbreviation used in the tables	Ethics	Site
Ambulance Service of NSW	ASNSW		Yes
Bellberry	BLLBRRY	Yes	
Calvary Mater Hospital Newcastle	CALVARY		Yes
Central Coast LHD	CCLHD		Yes
NSW Population & Health Services Research Ethics Committee	CINSW	Yes	
Greater Western LHD	WNSWLHD	Yes	Yes
Hammond Care	HCARE		Yes
Hunter New England LHD	HNELHD	Yes	Yes
Justice Health & Forensic Mental Health Network	JHFMHN	Yes	Yes
Mid North Coast LHD	MNCLHD		Yes
Murrumbidgee LHD	MLHD		Yes
Northern NSW LHD	NNSWLHD	Yes	Yes
Nepean Blue Mountains LHD	NBMLHD	Yes	Yes
Northern Sydney LHD	NSLHD	Yes	Yes
NSW Health Pathology	NSWHPTH		Yes
Royal Rehabilitation Centre Sydney HREC	RRCS	Yes	
Sydney Children's Hospitals Network	SCHN	Yes	Yes
South Eastern Sydney LHD	SESLHD	Yes	Yes
Sydney LHD (Concord Zone)	SLHD – CCD	Yes	Yes
Sydney LHD (RPAH Zone)	SLHD – RPA	Yes	Yes
Southern NSW LHD	SNSWLHD		Yes
St Vincent's Hospital	SVHN	Yes	Yes
South Western Sydney LHD	SWSLHD	Yes	Yes
Illawarra Shoalhaven LHD (joint committee with University of Wollongong)	ISLHD	Yes	Yes
Western Sydney LHD	WSLHD	Yes	Yes



For more information

This report has been prepared by the Research Ethics and Governance Unit in Office for Health and Medical Research.

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