OHMR Research Ethics and Governance Metrics Program



Metrics Activity Report for NSW PHOs

Reporting Period: Quarter 1 2022

01/01/2022 - 31/03/2022

NSW Office for Health and Medical Research





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 during the reporting period. 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
 - o 90 days for ethics, 60 days for governance
 - o Threshold changes
 - o >75% = Performing
 - 55%-75% = Underperforming
 - o <55% = Not performing</p>



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-toend 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	 Study Type = All Application Type = Greater than low risk Approval Type = Approved/ Approved with conditions within the reporting period
Exclusions	 Application Type = Low and negligible risk Approval Type = Not within the reporting period Migrated studies
Total Time:	lefined as the measurement of

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 during the reporting period (Quarter 1 2022) are shown in **Table 1**. During the reporting period, **197 studies** (greater than low risk pathway) were approved by an HREC with an average review time (total time) of **63 days**. Of these 197 studies, **74** (38%) 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) during the reporting period.

				Approval (Q1 than low risk a			
		9	Total Time 90 Day Benchmarl	c	Total Time (calenda		
NSW PHOs	Total Number of Applications	Count <90 Day Benchmark	% <90 Day Total Time Benchmark	Average Total Time (Days)	Average Research Office Time	Average Researcher Time	Count Request for Information
BLLBRRY	27	25	93%	54	27	27	2.1
CINSW	16	8	50%	82	40	42	1.8
HNELHD	22	19	86%	62	20	42	1.7
ISLHD	4	3	75%	80	50	30	1.5
JHFMHN	3	2	67%	134	61	73	1.0
NBMLHD	7	7	100%	70	46	24	1.0
NNSWLHD	2	2	100%	59	38	21	2.5
NSLHD	3	2	67%	80	28	52	2.3
SCHN	9	5	56%	85	45	40	1.8
SESLHD	10	10	100%	54	28	26	2.0
SLHD-CCD	3	3	100%	74	34	40	1.3
SLHD-RPA	34	34	100%	43	20	23	1.2
SVHN	10	8	80%	59	30	29	1.7
SWSLHD	18	15	83%	66	42	24	1.4
WNSWLHD	2	2	100%	43	43	-	0.5
WSLHD	27	19	70%	72	41	31	1.9
TOTAL	197	164	83%	63	32	31	1.7

				Approval (Q1 Clinical Trials			
		9	Total Time 90 Day Benchmar	k	Total Time (calenda		
NSW PHOs	Total Number of Applications	Count <90 Day Benchmark	% <90 Day Total Time Benchmark	Average Total Time (Days)	Average Research Office Time	Average Researcher Time	Count Request for Information
BLLBRRY	27	25	93%	54	27	27	2.1
CINSW	1	1	100%	53	29	24	1.0
HNELHD	7	7	100%	46	17	29	1.6
ISLHD	2	1	50%	91	53	38	2.0
NSLHD	2	1	50%	97	28	70	3.0
SCHN	3	1	33%	98	52	46	2.3
SESLHD	2	2	100%	73	39	35	2.5
SLHD-CCD	1	1	100%	77	48	29	2.0
SLHD-RPA	10	10	100%	50	24	26	1.0
SVHN	2	2	100%	58	39	19	1.0
SWSLHD	4	2	50%	84	39	46	1.8
WSLHD	13	10	77%	71	40	31	1.9
TOTAL	74	63	85%	62	31	31	1.9

Table 2. The 90 calendar days benchmark for the approval of clinical trials (greater than low risk) during the reporting period.

 Table 3. Breakdown of NSW PHO performances in clinical trial approvals (greater than low risk) during the reporting period by sponsor type

	C	ollaborative group			Commercial entity	1	Investigator-initiated				
NSW PHOs	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	53	2	38	61		
CINSW							1	29	53		
HNELHD	1	6	29	3	15	42	3	21	55		
ISLHD	1	62	104				1	44	77		
NSLHD				1	17	69	1	38	125		
SCHN				2	69	131	1	19	32		
SESLHD				1	38	64	1	39	82		
SLHD-CCD							1	48	77		
SLHD-RPA				1	21	51	9	25	50		
SVHN				1	43	58	1	35	58		
SWSLHD				1	29	53	3	42	95		
WSLHD				4	36	67	9	42	73		
Grand Total	2	34	67	39	29	58	33	34	66		

Table 4. Quarterly clinical trial approvals (greater than low risk) between 01/07/2021 and 31/03/2022, by sponsor type

		Q3 2021			Q4 2021		Q1 2022				
Sponsor Type	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	10	Time (days)(days)3087		8	25	41 2		34	67		
Commercial Entity	41	24	57	61	31	60	39	29	58		
Investigator Initiated	40	24	63	31	28	55	33	34	66		
Total	91	91 25 63		100	29	57	74	31	62		

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 01/07/2021 and 31/03/2022.

				Q3 2021				Q4 2021								Q1 2022					
		45 Day	Benchmai clock)	rk (with		ay Benchn thout cloo			45 Day	Benchma clock)	rk (with		ay Benchr ithout clo			45 Day	Benchmai clock)	rk (with		ay Benchm thout cloc	
	er of ns		ciocky	e	(001		Time	er of ns		ciocky	m	(**	e	Time	er of ns		clocky	m		ЭГ	-
NSW PHOs	Total Number Annlications	Count 45 Day Benchmark	% 45 Day Benchmark	Average Metric 3 Time (Days)	Count 90 Day Benchmark	% 90 Day Total Ti Benchmark	Average Total Tiı (Days)	Total Number Applications	Count 45 Day Benchmark	% 45 Day Benchmark	Average Metric Time (Days)	Count 90 Day Benchmark	% 90 Day Total Tim Benchmark	Average Total Tii (Days)	Total Number Applications	Count 45 Day Benchmark	% 45 Day Benchmark	Average Metric Time (Days)	Count 90 Day Benchmark	% 90 Day Total Tin Benchmark	Average Total Time (Days)
BLLBRRY	20	19	95%	25	18	90%	55	26	25	96%	26	23	88%	43	27	23	85%	27	25	93%	54
CINSW	21	21	100%	31	17	81%	84	15	13	87%	33	13	87%	108	16	11	69%	40	8	50%	82
HNELHD	35	33	94%	28	29	83%	86	37	37	100%	23	32	86%	63	22	21	95%	20	19	86%	62
ISLHD	6	4	67%	44	5	83%	72	6	4	67%	45	4	67%	92	4	1	25%	50	3	75%	80
JHFMHN	1	1	100%	38	0	0%	602	1	0	0%	76	0	0%	134	3	0	0%	61	2	67%	134
NBMLHD	9	7	78%	38	8	89%	70	8	4	50%	42	6	75%	105	7	1	14%	46	7	100%	70
NNSWLHD	3	1	33%	57	2	67%	232	2	2	100%	36	2	100%	70	2	1	50%	38	2	100%	59
NSLHD	5	5	100%	25	4	80%	56	7	7	100%	15	7	100%	38	3	3	100%	28	2	67%	80
SCHN	14	14	100%	26	13	93%	58	17	10	59%	38	11	65%	74	9	4	44%	45	5	56%	85
SESLHD	13	12	92%	25	13	100%	38	17	15	88%	31	15	88%	69	10	10	100%	28	10	100%	54
SLHD-CCD	17	17	100%	26	8	47%	121	12	12	100%	24	11	92%	56	3	2	67%	34	3	100%	74
SLHD-RPA	57	56	98%	15	47	82%	68	41	41	100%	15	39	95%	42	34	34	100%	20	34	100%	43
SVHN	38	36	95%	26	32	84%	64	33	31	94%	25	33	100%	41	10	10	100%	30	8	80%	59
SWSLHD	22	22	100%	19	20	91%	63	22	19	86%	32	16	73%	82	18	12	67%	42	15	83%	66
WNSWLHD	11	10	91%	32	11	100%	11	4	4	100%	32	4	100%	42	2	1	50%	43	2	100%	43
WSLHD	32	30	94%	32	25	78%	61	21	15	71%	39	18	86%	67	27	18	67%	41	19	70%	72
TOTAL	30 4	288	95%	26	252	83%	72	269	239	89%	28	234	87%	62	197	152	77%	32	164	83%	63



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	 Study Type = All Application Type = Greater than low risk Approval Type = "Authorised" or "authorised with conditions" within the reporting period
Exclusions	 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 during the reporting period (Quarter 1 2022) are shown in **Table 6**. During the reporting period, **418** studies (greater than low risk pathway) were authorised in NSW PHOs with an average review time (total time) of **48 days**. Of these 417 studies, **195** (47%) 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) during the reporting period.

		SSA Approvals (Q1 2022) All greater than low risk applications													
		60 Day Bo	enchmark (with	out clock)	Tota	al Time Breakdo	own (calendar c	n (calendar days)							
NSW PHOs	Total Number of Applications	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%	19	11	4	1	3							
CCLHD	16	14	88%	35	8	7	0	21							
HNELHD	40	33	83%	33	8	6	1	19							
ISLHD	10	10	100%	11	7	2	0	1							
JHFMHN	2	2	100%	40	32	9	-	-							
MLHD	3	3	100%	27	12	5	0	10							
MNCLHD	3	3	100%	26	7	3	13	4							
NBMLHD	18	12	67%	56	14	8	8	26							
NNSWLHD	3	3	100%	25	9	5	11	-							
NSLHD	24	16	67%	61	19	8	0	34							
NSWHPTH	5	3	60%	56	7	38	0	10							
SCHN	19	11	58%	66	18	15	1	33							
SESLHD	35	25	71%	42	10	7	-	24							
SLHD-CCD	21	21	100%	25	9	5	-	11							
SLHD-RPA	47	41	87%	32	2	9	5	16							
SNSWLHD	3	1	33%	74	2	-	41	32							
SVHN	29	18	62%	50	13	10	-	27							
SWSLHD	56	32	57%	73	15	11	0	46							
WNSWLHD	8	7	88%	31	2	16	5	8							
WSLHD	63	53	84%	37	12	8	3	15							
TOTAL	418	321	77%	44	11	9	2	23							

			SSA /	Approvals (C Clinical Tri				
		60 Day	Benchmark (without o	clock)	Tot	al Time Breakdo	own (calendar d	lays)
NSW PHOs	Total Number of Applications	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	8	8	100%	12	8	3	1	0
CCLHD	6	5	83%	28	3	8	0	17
FWLHD	0	0	-	-	-	-	-	-
HNELHD	18	14	78%	37	7	5	1	25
ISLHD	4	4	100%	19	13	4	0	3
JHFMHN	0	0	-	-	-	-	-	-
MLHD	1	1	100%	14	8	6	0	0
MNCLHD	1	1	100%	34	7	0	14	13
NBMLHD	8	3	38%	73	23	13	7	30
NNSWLHD	2	2	100%	38	14	7	17	0
NSLHD	12	11	92%	50	24	6	0	20
NSWHPTH	0	0	-	-	-	-	-	-
SCHN	9	5	56%	80	16	16	1	46
SESLHD	11	7	64%	45	11	11	0	23
SLHD-CCD	8	8	100%	30	19	4	0	7
SLHD-RPA	10	7	70%	44	2	9	13	21
SNSWLHD	0	0	-	-	-	-	-	-
SVHN	23	15	65%	43	12	11	0	21
SWSLHD	29	13	45%	95	17	14	0	63
WNSWLHD	2	2	100%	21	2	5	0	14
WSLHD	43	41	95%	27	9	5	3	9
TOTAL	195	147	75%	47	12	8	2	24

 Table 7: The 60 calendar days benchmark for the authorisation of clinical trials (greater than low risk) during the reporting period.

	C	collaborative group			Commercial entity		Investigator-initiated				
NSW PHOs	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	1	6	4	10	13	3	7	14		
CCLHD	3	1	11	1	3	16	2	7	60		
HNELHD	1	8	69	8	4	11	9	9	57		
ISLHD	2	22	22	2	4	17					
MLHD	1	8	14								
MNCLHD				1	7	34					
NBMLHD	1	61	77	5	14	56	2	26	113		
NNSWLHD	1	12	34	1	16	41					
NSLHD	9	25	48	2	23	43	1	15	78		
SCHN	1	3	40	4	6	35	4	31	134		
SESLHD	4	7	20	5	16	53	2	4	73		
SLHD-CCD	1	20	40	5	19	29	2	20	30		
SLHD-RPA				6	2	53	4	2	31		
SVHN	3	17	53	12	11	44	8	11	39		
SWSLHD	5	22	94	15	13	53	9	22	164		
WNSWLHD	1	1	35	1	3	6					
WSLHD	1	1	5	27	9	22	15	11	36		
Total	35	17	44	99	10	35	61	13	68		

Table 8. NSW PHO performances in clinical trial authorisations (greater than low risk) during the reporting period, by sponsor type

		Q3 2021			Q4 2021			Q1 2022	
Sponsor Type	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	48	9	47 48		9	38	35	17	44
Commercial Entity	100	10	37	100	10	30	99	10	35
Investigator Initiated	61	61 11		61	11	82	61	13	68
Total	209	10	53	209	10	47	195	12	47

Table 9. Quarterly clinical trial authorisations (greater than low risk applications) approved during the reporting period, by sponsor type

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 06/01/2021 and 31/03/2022.

				Q3 20	21			Q4 2021						Q1 2022							
	Applications		ay Benchi with clock			Day Benchn vithout cloc	:k)	Applications	15	Day Bench (with cloc			Day Benchr without clo		ations		Day Bench vith clock)	mark	60 Day Benchmark (without clock)		
LHD	Number of Applic	Count of 15 Day Benchmark	% 15 Day Benchmark	Average Metric Time (Days)	Count of 60 Day Benchmark	% 60 Day Total Time Benchmark	Average Total Time (Days)	Number of Applic	Count of 15 Day Benchmark	% 15 Day Benchmark	Average Metric Time (Days)	Count of 60 Day Benchmark	% 60 Day Total Time Benchmark	Average Total Time (Days)	Number of Applications	Count of 15 Day Benchmark	% 15 Day Benchmark	Average Metric Time (Days)	Count of 60 Day Benchmark	% 60 Day Total Time Benchmark	Average Total Time (Days)
ASNSW	0	0	-	-	0	-	-	0	0	-	-	0	-	-	0	0	-	-	0	-	-
CALVARY	10	7	70%	11	9	90%	20	13	12	92%	8	13	100%	13	13	9	69%	11	13	100%	19
CCLHD	7	2	29%	25	4	57%	130	20	14	70%	19	15	75%	63	16	15	94%	8	14	88%	35
FWLHD	0	0	-	-	0	-	-	0	0	-	-	0	-	-	0	0	-	-	0	-	-
HNELHD	33	33	100%	5	28	85%	42	57	46	81%	10	43	75%	54	40	35	88%	8	33	83%	33
ISLHD	18	16	89%	5	16	89%	34	17	17	100%	2	17	100%	11	10	9	90%	7	10	100%	11
JHFMHN	0	0	-	-	0	-	-	0	0	-	-	0	-	-	2	0	0%	32	2	100%	40
MLHD	4	4	100%	6	4	100%	19	4	3	75%	12	4	100%	21	3	3	100%	12	3	100%	27
MNCLHD	6	4	67%	13	1	17%	177	8	6	75%	16	6	75%	56	3	3	100%	7	3	100%	26
NBMLHD	19	9	47%	21	10	53%	102	23	12	52%	16	16	70%	71	18	11	61%	14	12	67%	56
NNSWLHD	4	2	50%	24	4	100%	27	6	4	67%	12	6	100%	25	3	2	67%	9	3	100%	25
NSLHD	26	26	100%	6	18	69%	64	38	37	97%	6	24	63%	59	24	10	42%	19	16	67%	61
NSWHPTH	11	7	64%	13	6	55%	80	5	5	100%	6	2	40%	122	5	5	100%	7	3	60%	56
SCHN	35	27	77%	10	19	54%	68	36	21	58%	18	14	39%	85	19	11	58%	18	11	58%	66
SESLHD	44	37	84%	7	30	68%	57	35	27	77%	10	26	74%	81	35	27	77%	10	25	71%	42
SLHD-CCD	20	18	90%	9	13	65%	61	29	27	93%	7	23	79%	59	21	15	71%	9	21	100%	25
SLHD-RPA	45	37	82%	7	33	73%	49	60	56	93%	4	49	82%	38	47	47	100%	2	41	87%	32
SNSWLHD	7	3	43%	37	5	71%	50	0	0	-	-	0	-	-	3	3	100%	2	1	33%	74
SVHN	33	25	76%	10	23	70%	61	46	36	78%	13	31	67%	79	29	22	76%	13	18	62%	50
SWSLHD	64	63	98%	5	40	63%	103	60	46	77%	11	40	67%	58	56	35	63%	15	32	57%	73
WNSWLHD	14	14	100%	1	14	100%	10	15	15	100%	3	14	93%	23	8	8	100%	2	7	88%	31
WSLHD	71	66	93%	9	59	83%	62	75	69	92%	8	61	81%	43	63	49	78%	12	53	84%	37
TOTAL	471	400	85%	9	336	71%	65	547	453	83%	10	404	74%	56	418	319	76%	11	321	77%	44

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

Human Research Ethics Committee/ Research Governance Office Name	s 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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