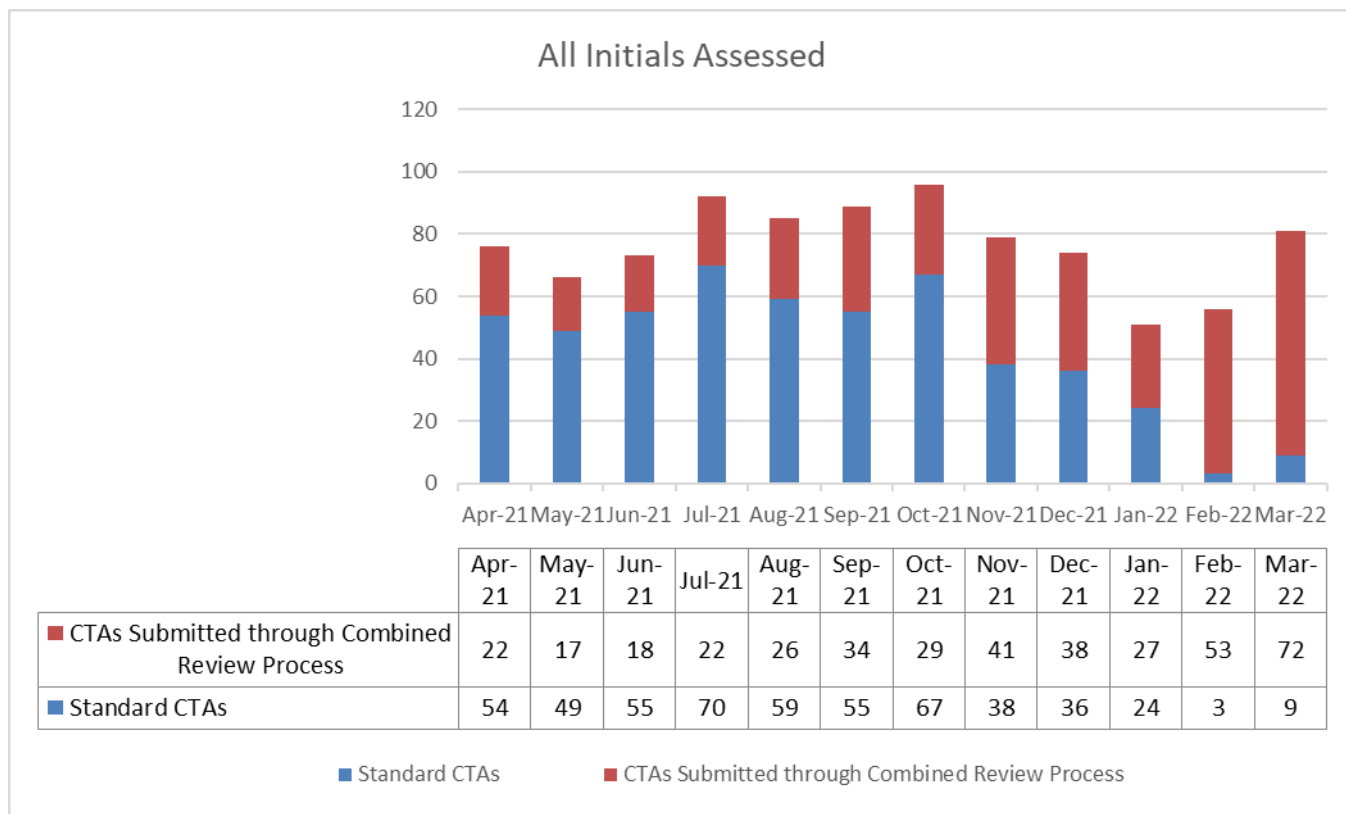
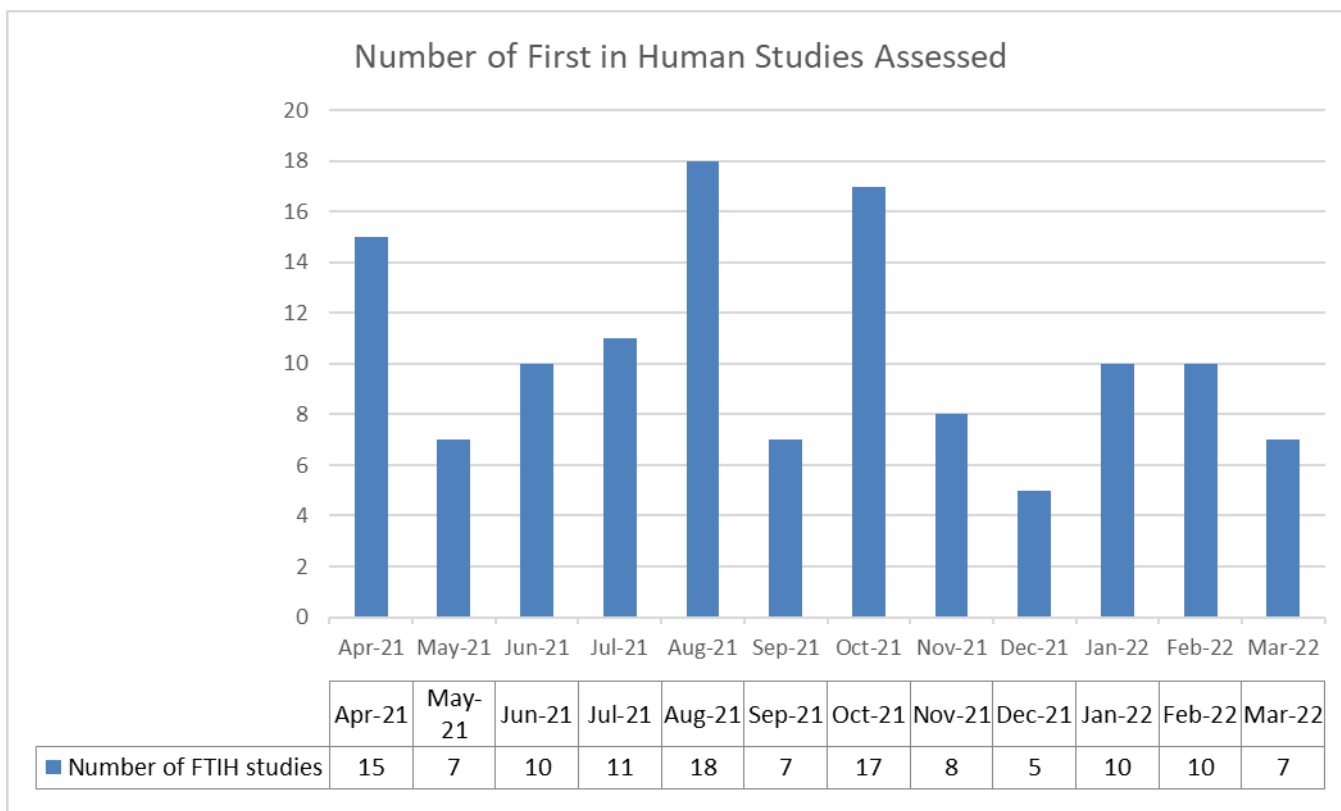


Clinical trials for medicines: authorisation assessment performance



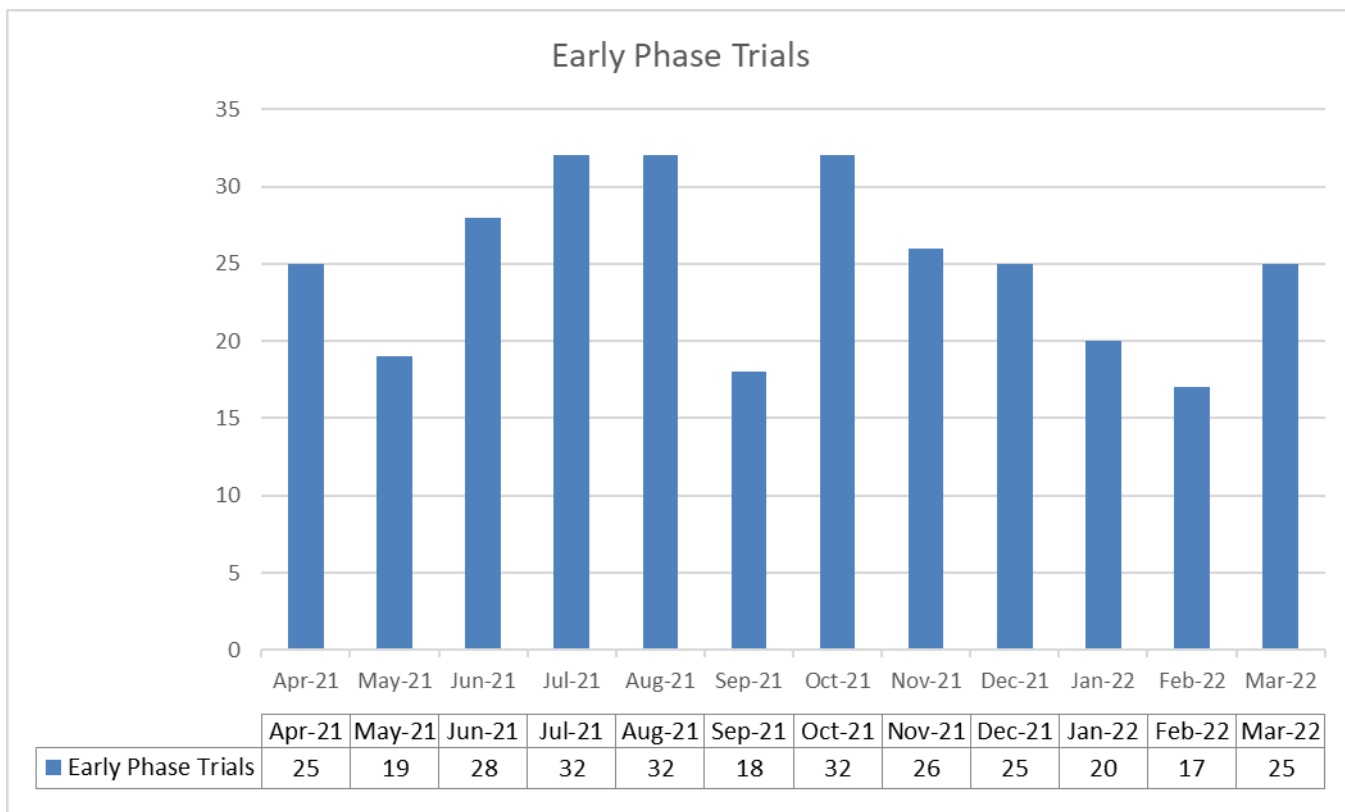
	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22	Feb-22	Mar-22
Standard CTAs	54	49	55	70	59	55	67	38	36	24	3	9
CTAs Submitted through Combined Review Process	22	17	18	22	26	34	29	41	38	27	53	72
Total	76	66	73	92	85	89	96	79	74	51	56	81



	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22	Feb-22	Mar-22
Number of FTIH studies	15	7	10	11	18	7	17	8	5	10	10	7

* This data also includes applications submitted through the Combined Review process.

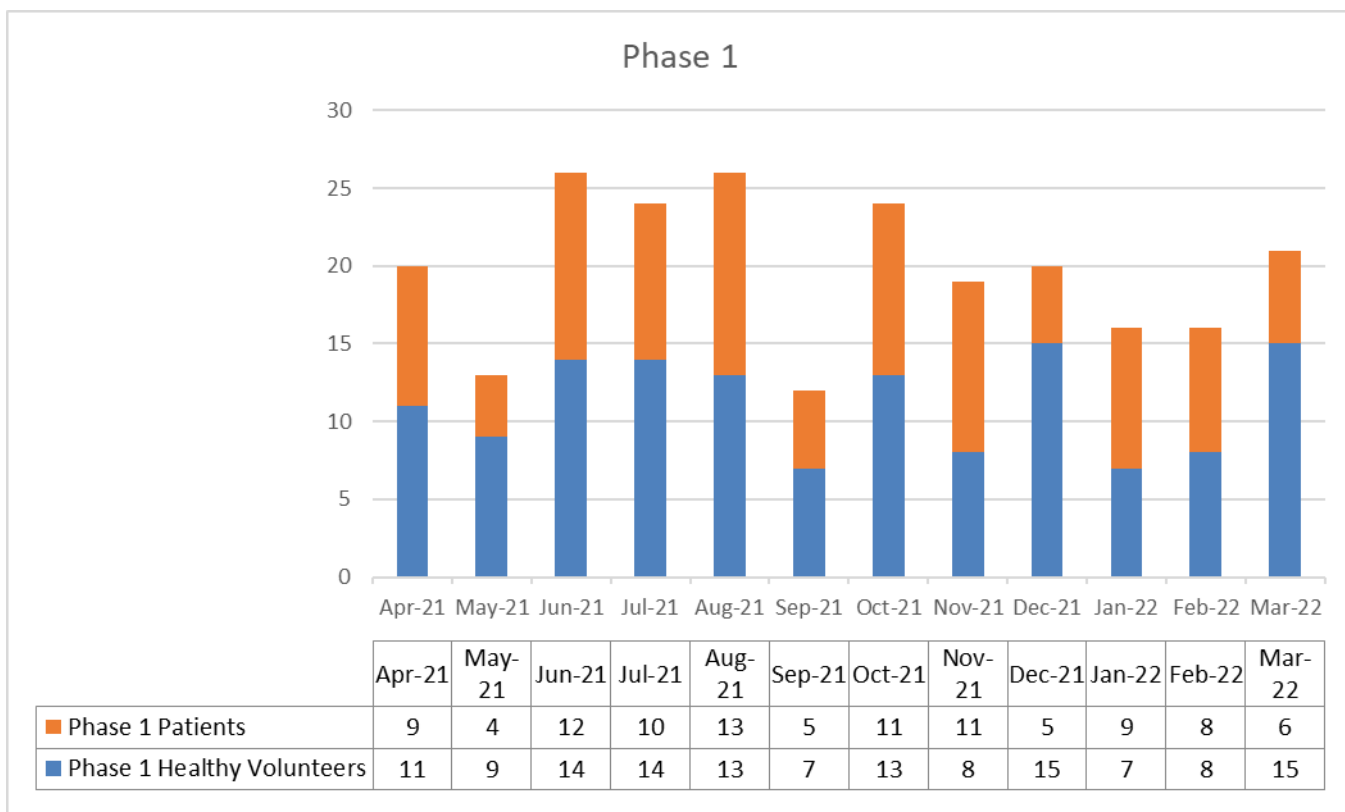
(FIH= First In Human)



	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22	Feb-22	Mar-22
Early Phase Trials (Trials with a Phase 1 element)	25	19	28	32	32	18	32	26	25	20	17	25

* This data also includes applications submitted through the Combined Review process.

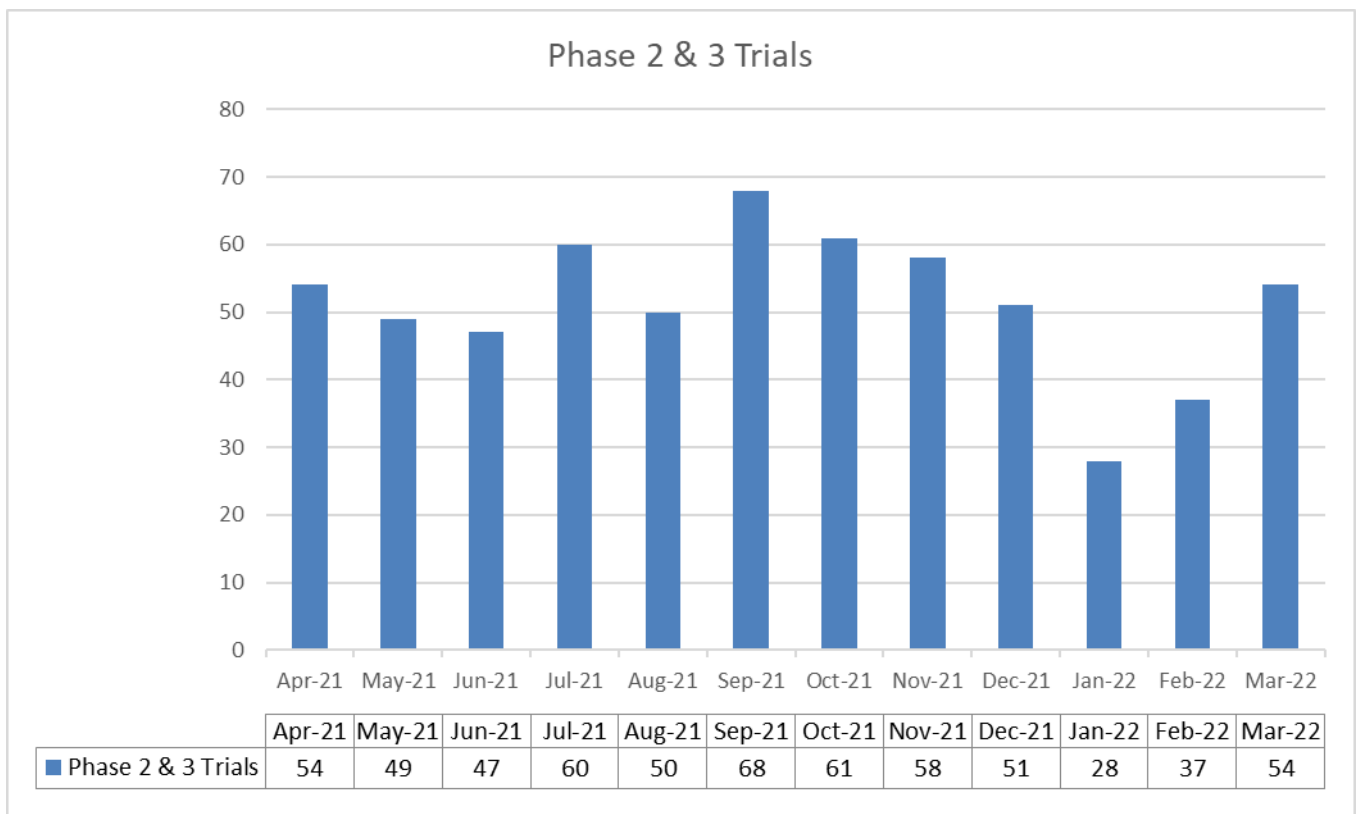
* This data represents clinical trials where the Sponsor has declared a Phase 1 element (e.g. Phase 1/2 trials).



	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22	Feb-22	Mar-22
Phase 1 Healthy Volunteers	11	9	14	14	13	7	13	8	15	7	8	15
Phase 1 Patients	9	4	12	10	13	5	11	11	5	9	8	6
Total	20	13	26	24	26	12	24	19	20	16	16	21

* This data also includes applications submitted through the Combined Review process.

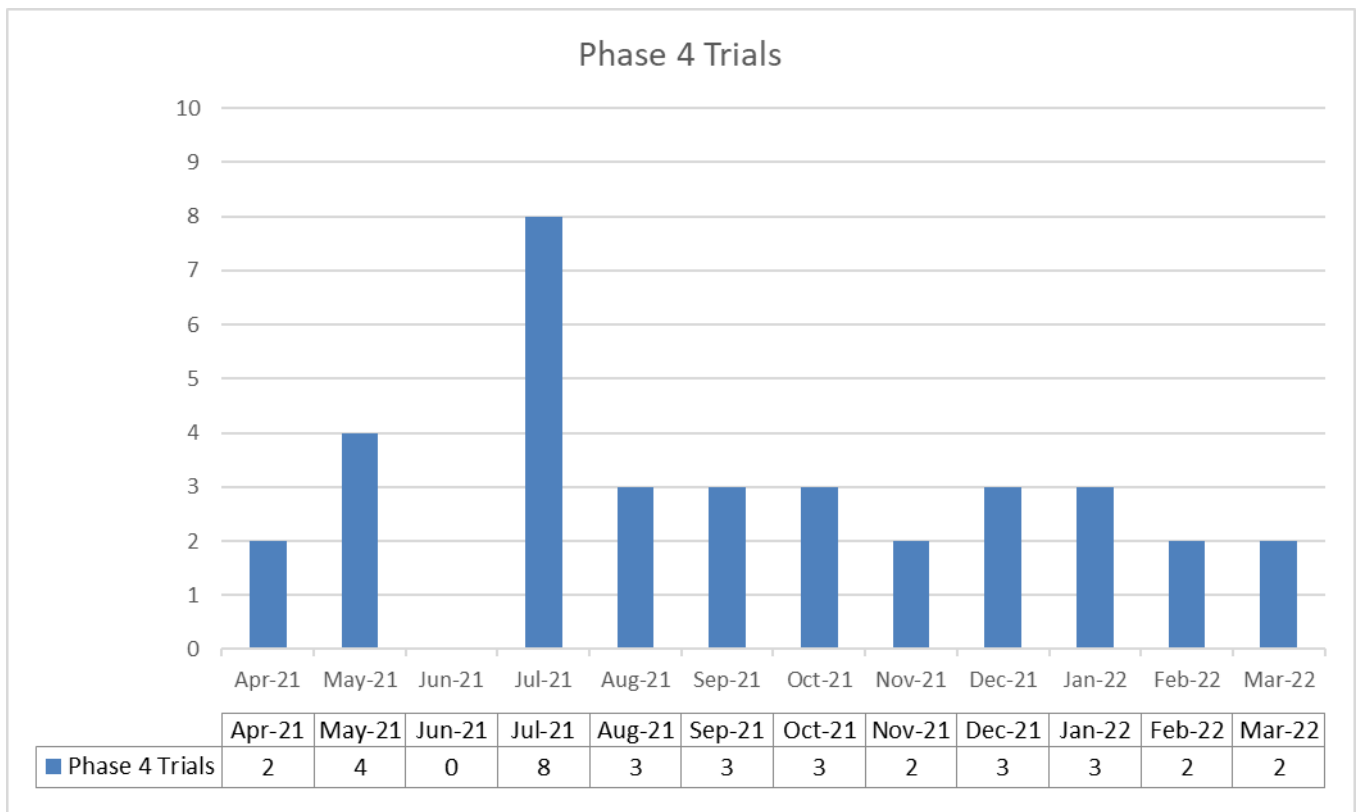
* This data represents clinical trials the Sponsor has declared as Phase 1 only.



	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22	Feb-22	Mar-22
Phase 2 & 3 Trials	54	49	47	60	50	68	61	58	51	28	37	54

* This data also includes applications submitted through the Combined Review process.

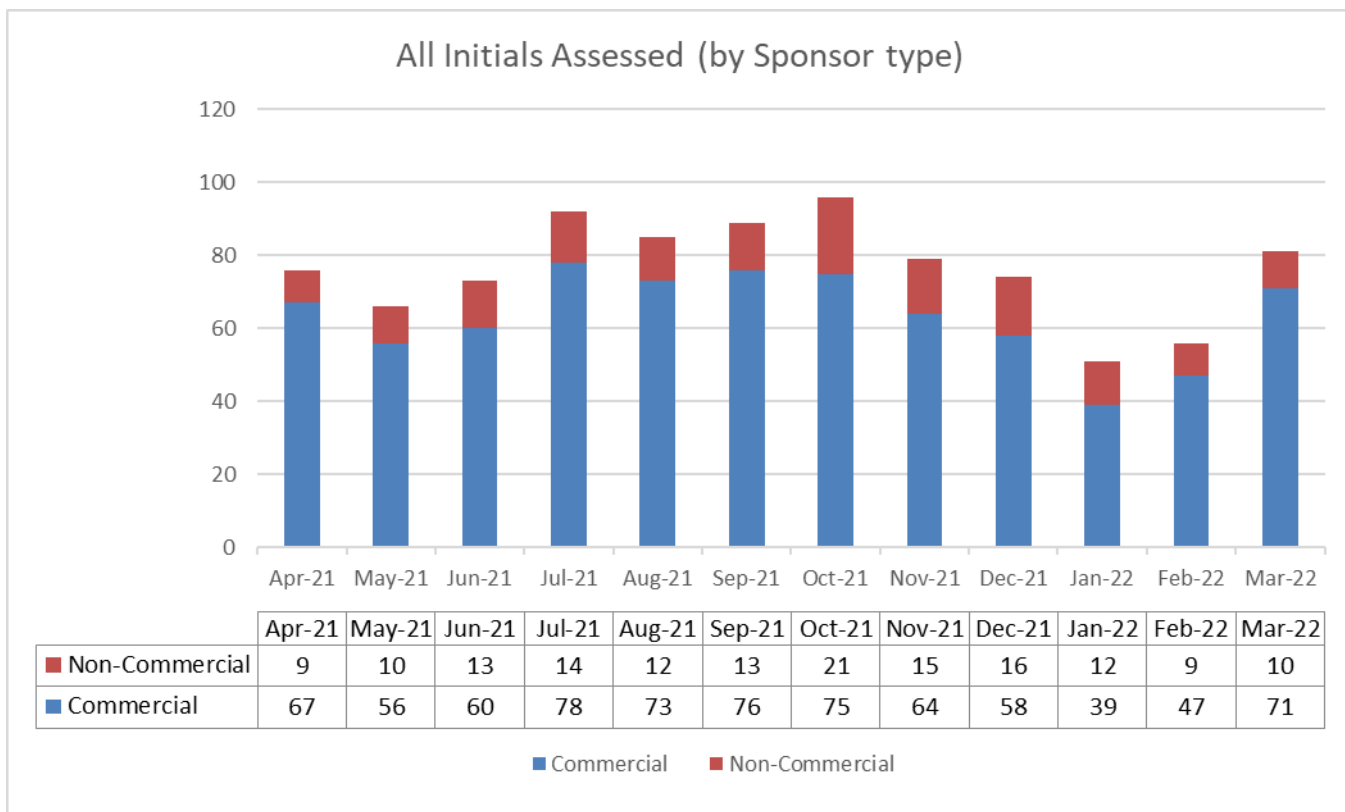
* This data represents clinical trials where the Sponsor has declared a Phase 2 or 3 element.



	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22	Feb-22	Mar-22
Phase 4 Trials	2	4	0	8	3	3	3	2	3	3	2	2

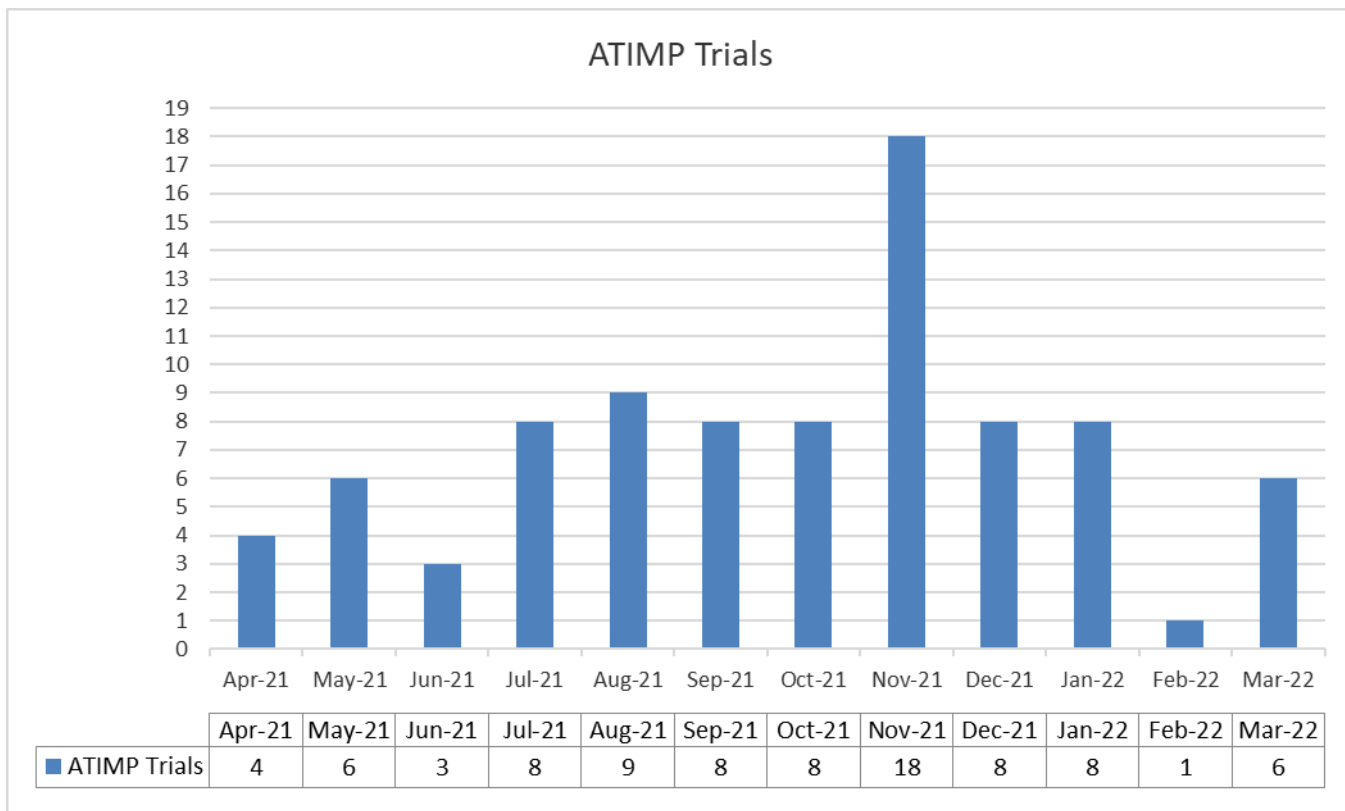
* This data also includes applications submitted through the Combined Review process.

* This data represents clinical trials the Sponsor has declared as Phase 4.



	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22	Feb-22	Mar-22
Commercial	67	56	60	78	73	76	75	64	58	39	47	71
Non-Commercial	9	10	13	14	12	13	21	15	16	12	9	10
Total	76	66	73	92	85	89	96	79	74	51	56	81

* This data also includes applications submitted through the Combined Review process.

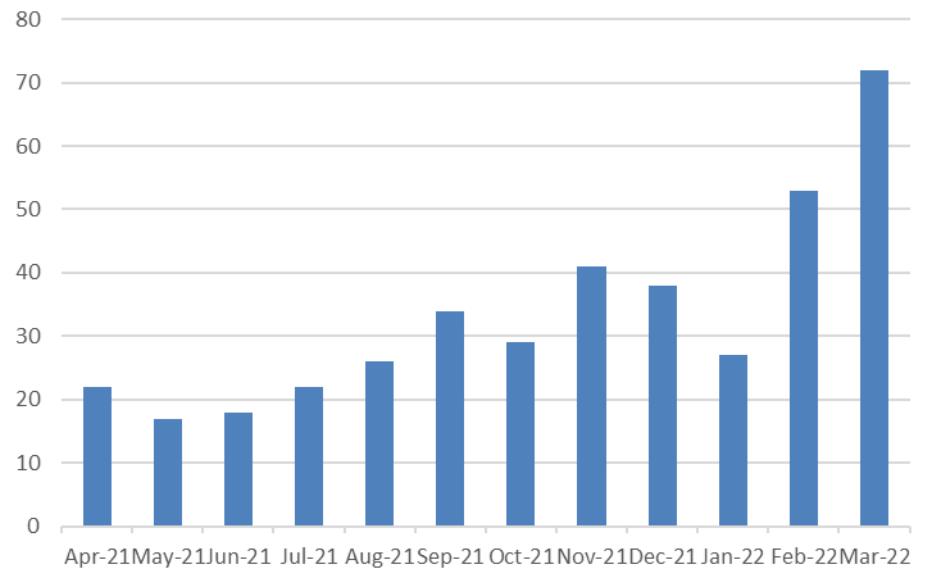


	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22	Feb-22	Mar-22
ATIMP Trials	4	6	3	8	9	8	8	18	8	8	1	6

* This data also includes applications submitted through the Combined Review process.

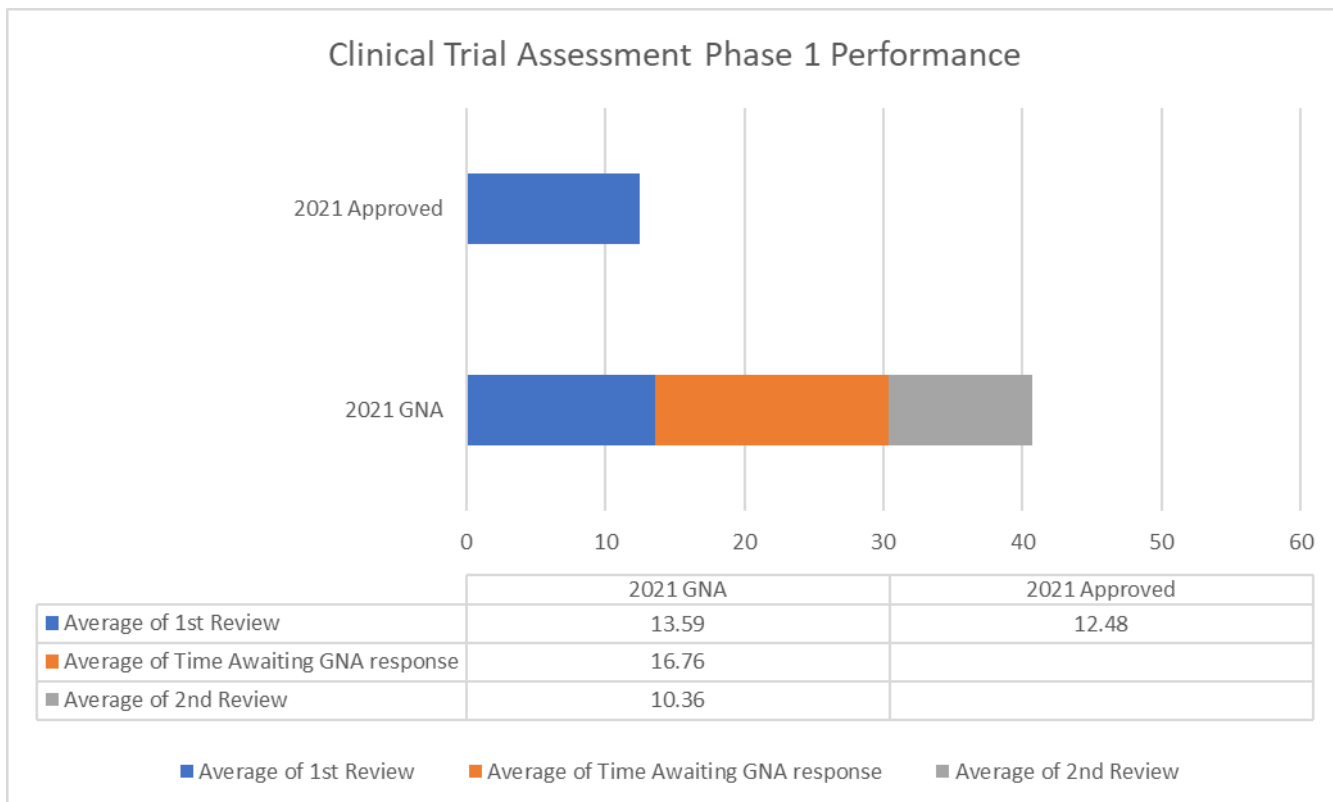
*This data reflects initial trial submissions including an advanced therapy investigational medicinal product (ATIMP). It does not reflect ATIMPs added to ongoing trials as a substantial amendment.

Number of Combined Review Applications Assessed



	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22	Feb-22	Mar-22
■ Number of Combined Review studies	22	17	18	22	26	34	29	41	38	27	53	72

	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22	Feb-22	Mar-22
Number of CWoW studies	22	17	18	22	26	34	29	41	38	27	53	72



	2021 GNA	2021 Approved
Average time for 1st Review	13.59	12.48
Average time awaiting GNA response from sponsor	16.76	-
Average time for 2nd Review	10.36	-

*Time is shown in days.

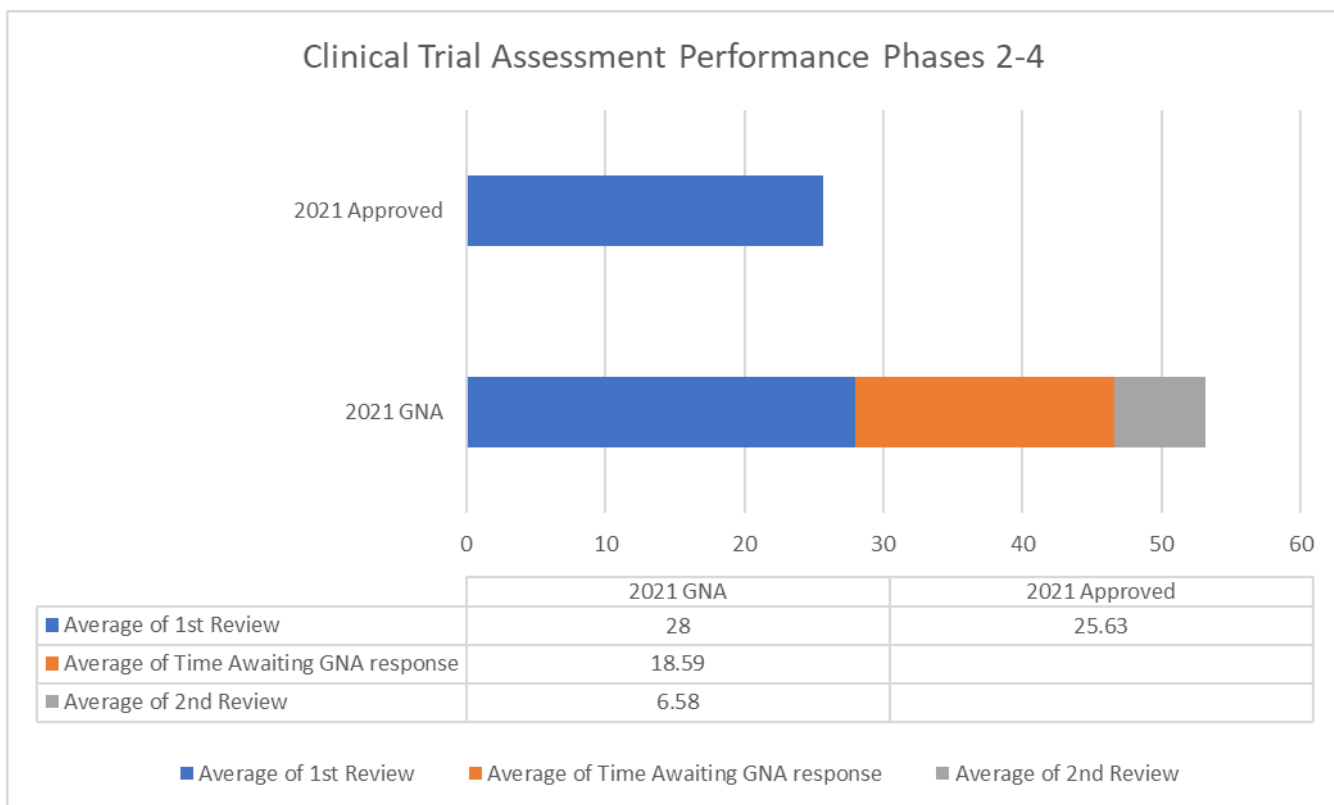
*This data represents a rolling average of applications determined in the financial year of 1st April 2021 – 31st March 2022 (inclusive).

* The data includes Phase 1 trials in Healthy Volunteer eligible for expedited review (average 14-days for initial assessment versus statutory timeframe of 30 days for initial assessment and 60 days for final decision).

*This data includes COVID-19 trials.

* This data does not include applications submitted through the Combined Review process.

(GNA = Grounds for non-acceptance)



	2021 GNA	2021 Approved
Average time for 1st Review	28	25.63
Average time awaiting GNA response from sponsor	18.59	-
Average time for 2nd Review	6.58	-

*Time is shown in days.

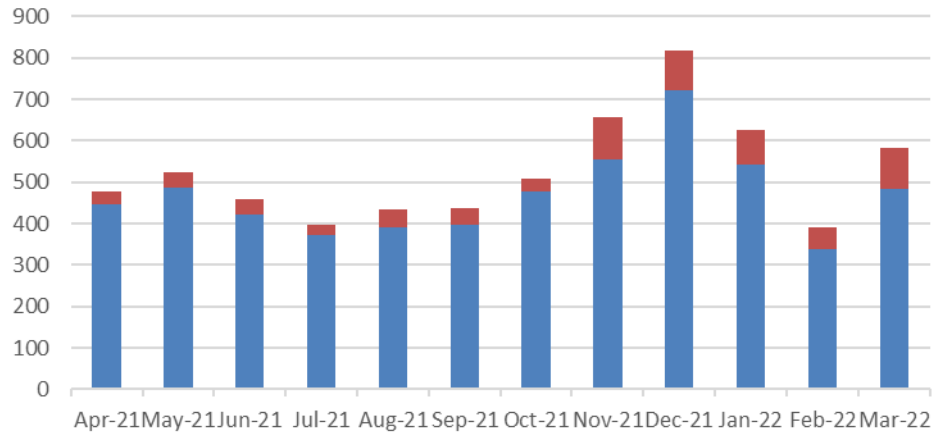
*This data represents a rolling average of applications determined in the financial year of 1st April 2021 – 31st March 2022 (inclusive).

*This data includes COVID-19 trials.

* This data does not include applications submitted through the Combined Review process.

(GNA = Grounds for non-acceptance)

All Substantial Amendments Assessed



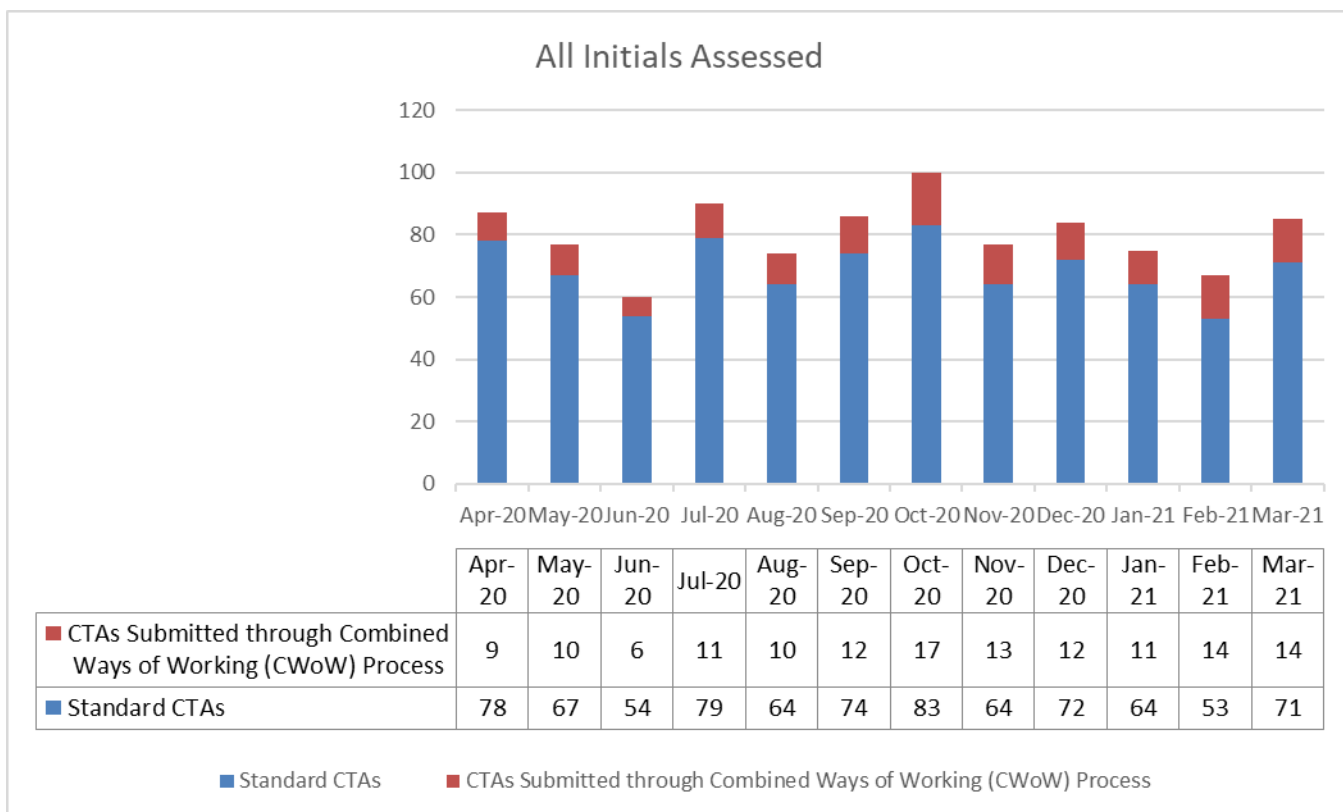
	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22	Feb-22	Mar-22
■ Substantial Amendments Submitted through Combined Review Process	29	35	37	26	43	41	31	103	95	83	54	99
■ Standard Substantial Amendments	448	488	423	372	390	396	477	555	723	543	337	485

■ Standard Substantial Amendments

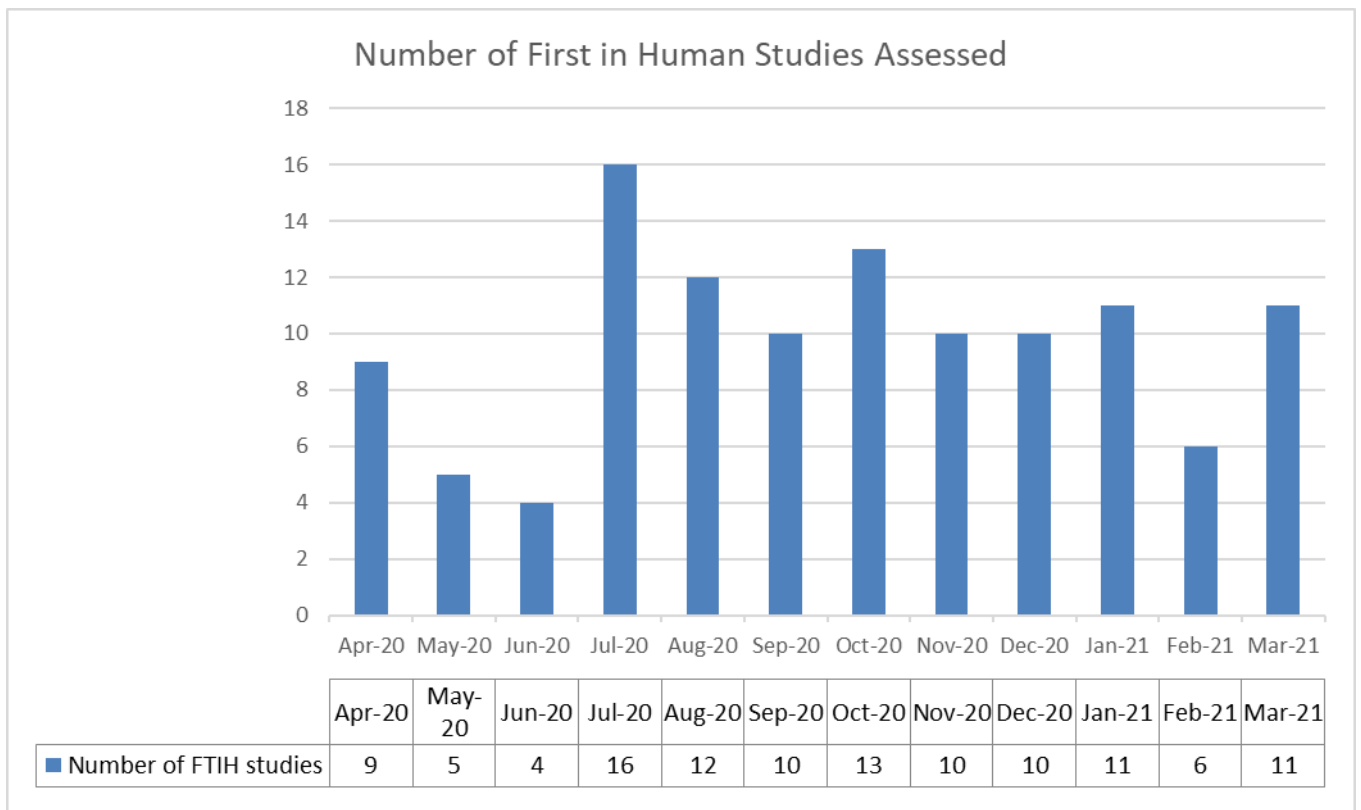
	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22	Feb-22	Mar-22
Standard Substantial Amendments	448	488	423	372	390	396	477	555	723	543	337	485
Substantial Amendments Submitted through Combined Review Process	29	35	37	26	43	41	31	103	95	83	54	99
Total	477	523	460	398	433	437	508	658	818	626	391	584

Annex 1 – Data for financial year 2020-2021

Clinical trials for medicines: authorisation assessment performance



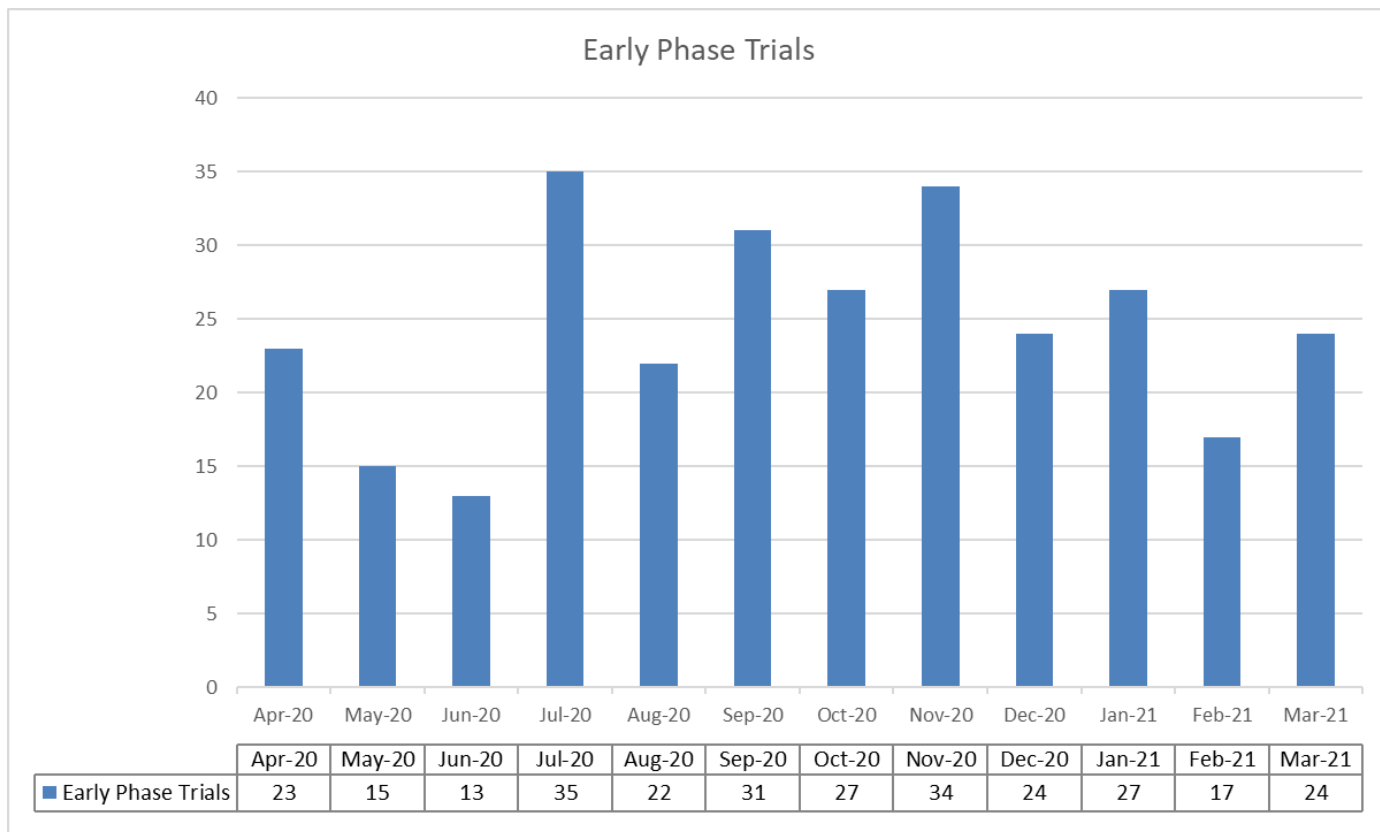
	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	Jan-21	Feb-21	Mar-21
Standard CTAs	78	67	54	79	64	74	83	64	72	64	53	71
CTAs Submitted through Combined Ways of Working (CWoW) Process	9	10	6	11	10	12	17	13	12	11	14	14
Total	87	77	60	90	74	86	100	77	84	75	67	85



	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	Jan-21	Feb-21	Mar-21
Number of FIH studies	9	5	4	16	12	10	13	10	10	11	6	11

* This data also includes applications submitted through the Combined Ways of Working (CWoW) process.

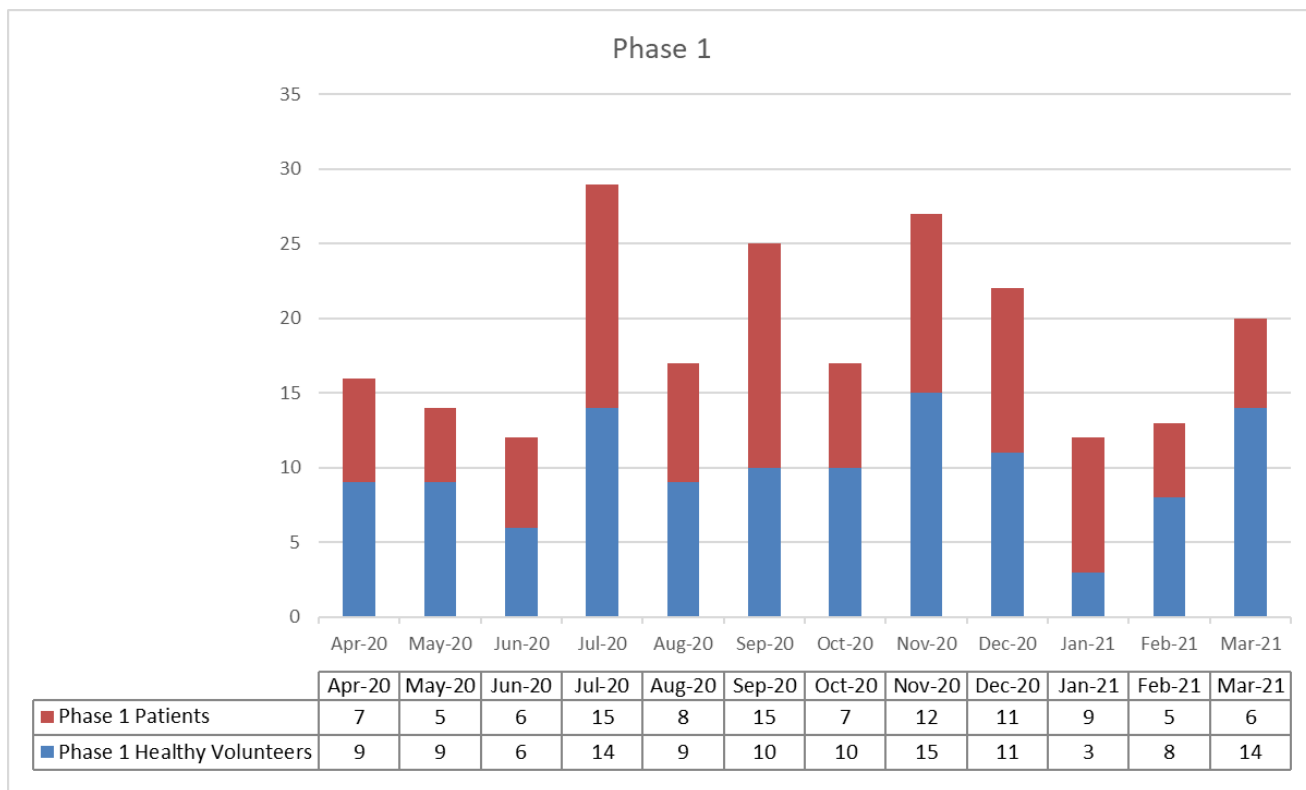
(FIH= First In Human)



	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	Jan-21	Feb-21	Mar-21
Early Phase Trials (Trials with a Phase 1 element)	23	15	13	35	22	31	27	34	24	27	17	24

* This data also includes applications submitted through the Combined Ways of Working (CWoW) process.

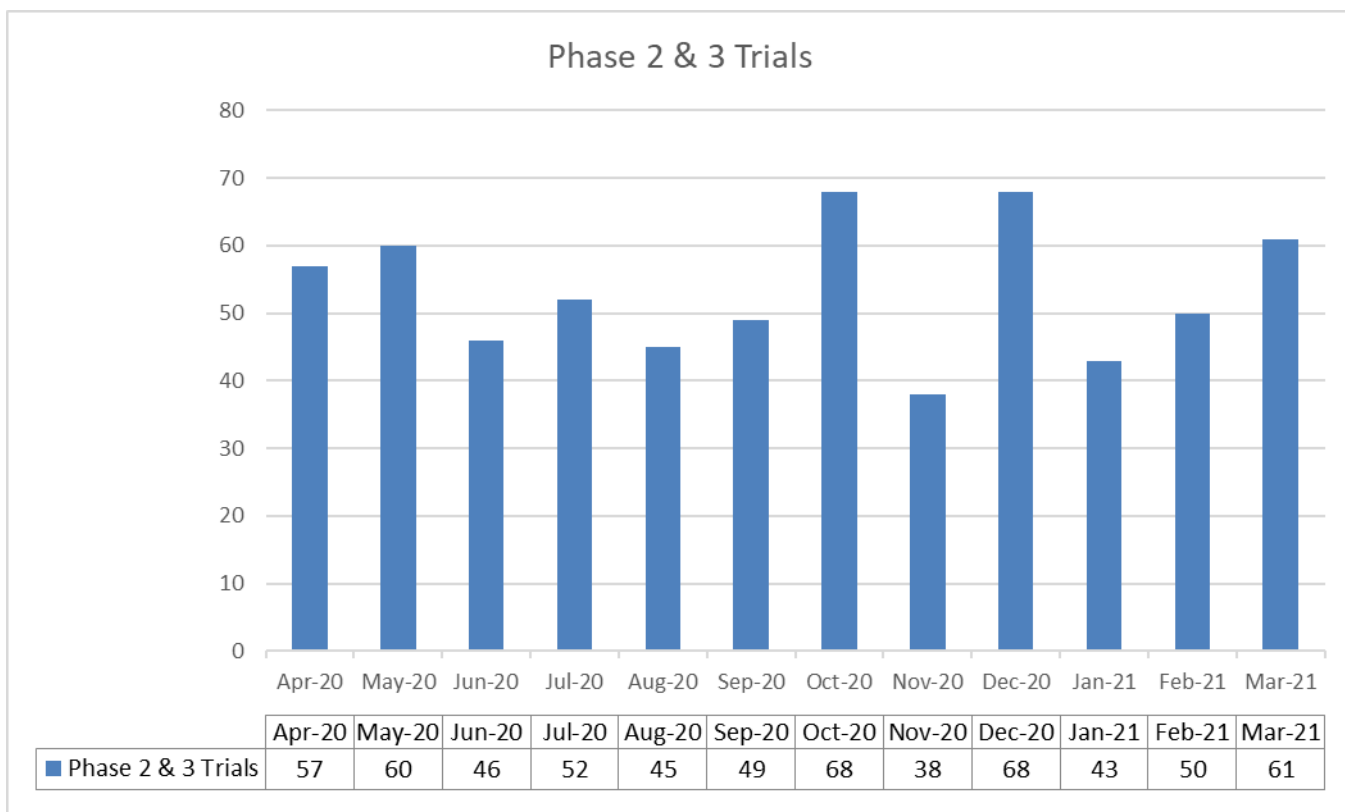
* This data represents clinical trials where the Sponsor has declared a Phase 1 element (e.g. Phase 1/2 trials).



	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	Jan-21	Feb-21	Mar-21
Phase 1 Healthy Volunteers	9	9	6	14	9	10	10	15	11	3	8	14
Phase 1 Patients	7	5	6	15	8	15	7	12	11	9	5	6
Total	16	14	12	29	17	25	17	27	22	12	13	20

* This data also includes applications submitted through the Combined Ways of Working (CWoW) process.

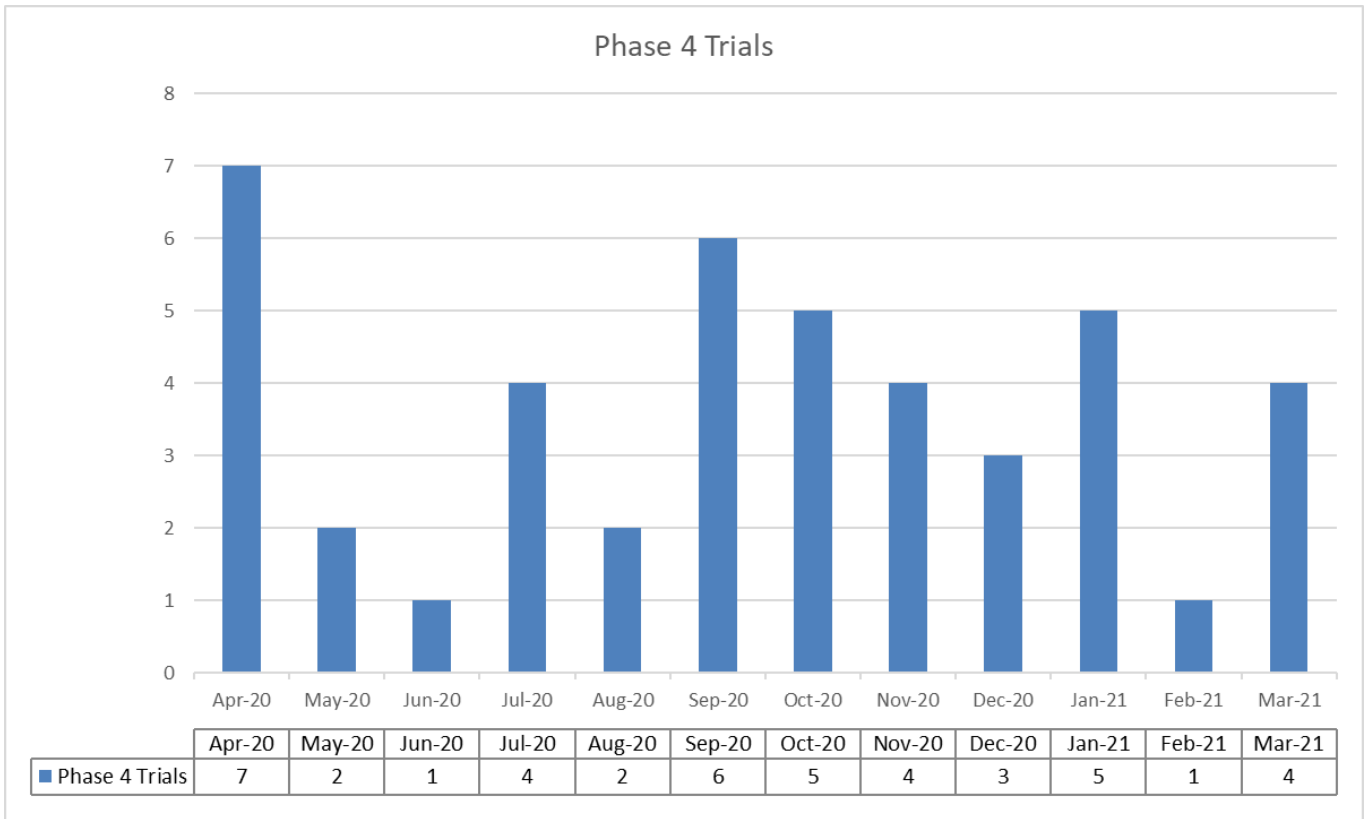
* This data represents clinical trials the Sponsor has declared as Phase 1 only.



	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	Jan-21	Feb-21	Mar-21
Phase 2 & 3 Trials	57	60	46	52	45	49	68	38	68	43	50	61

* This data also includes applications submitted through the Combined Ways of Working (CWoW) process.

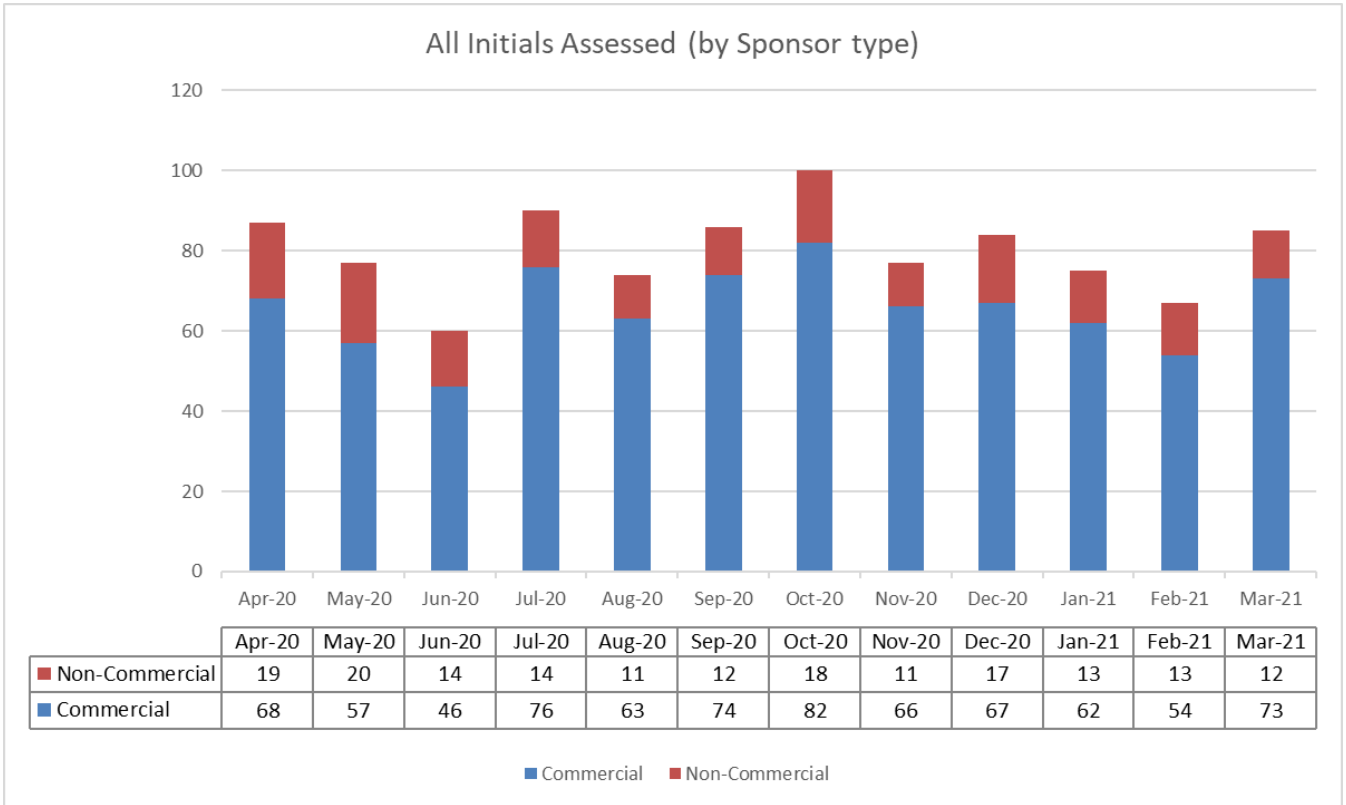
* This data represents clinical trials where the Sponsor has declared a Phase 2 or 3 element.



	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	Jan-21	Feb-21	Mar-21
Phase 4 Trials	7	2	1	4	2	6	5	4	3	5	1	4

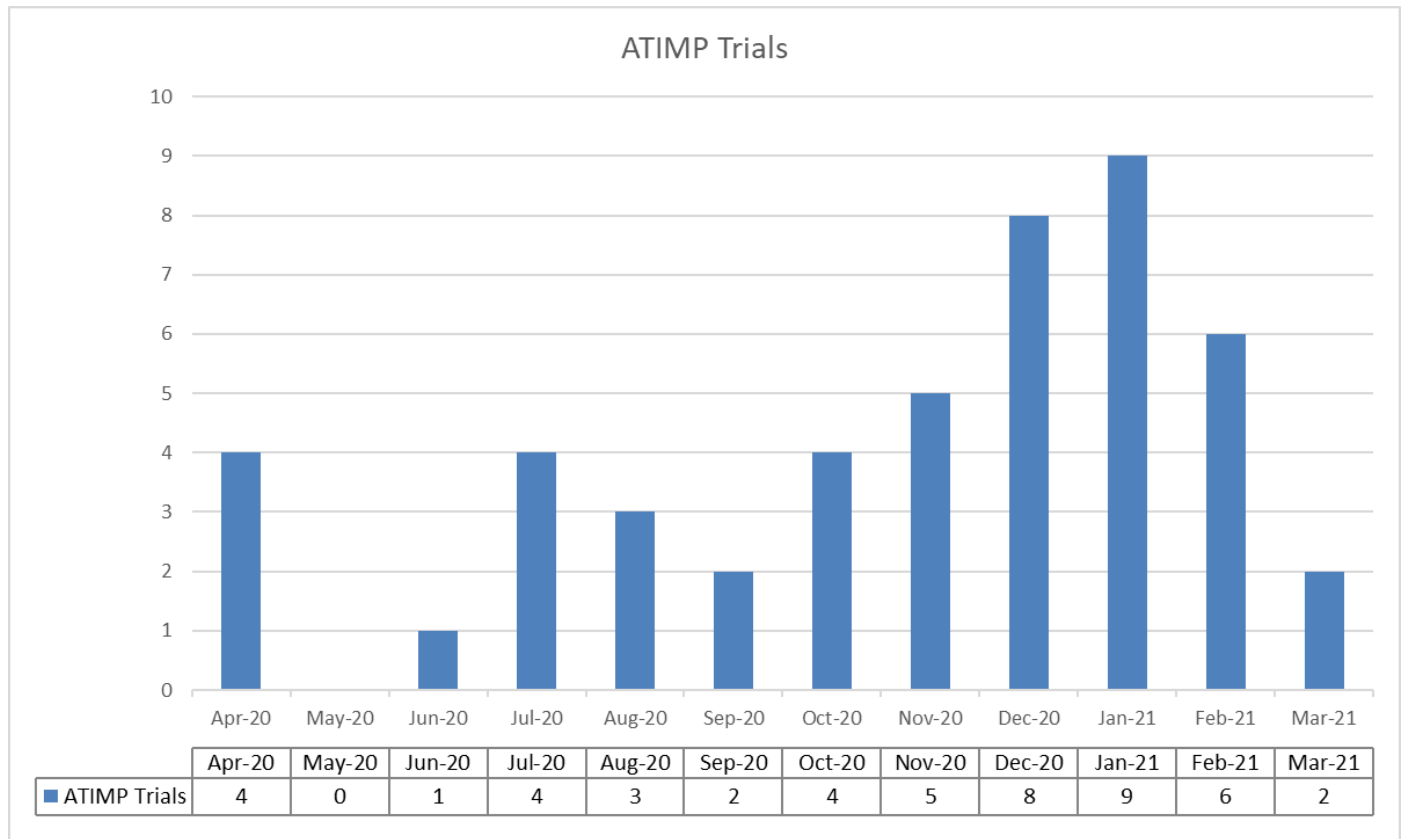
* This data also includes applications submitted through the Combined Ways of Working (CWoW) process.

* This data represents clinical trials the Sponsor has declared as Phase 4.



	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	Jan-21	Feb-21	Mar-21
Commercial	68	57	46	76	63	74	82	66	67	62	54	73
Non-Commercial	19	20	14	14	11	12	18	11	17	13	13	12
Total	87	77	60	90	74	86	100	77	84	75	67	85

* This data also includes applications submitted through the Combined Ways of Working (CWoW) process.

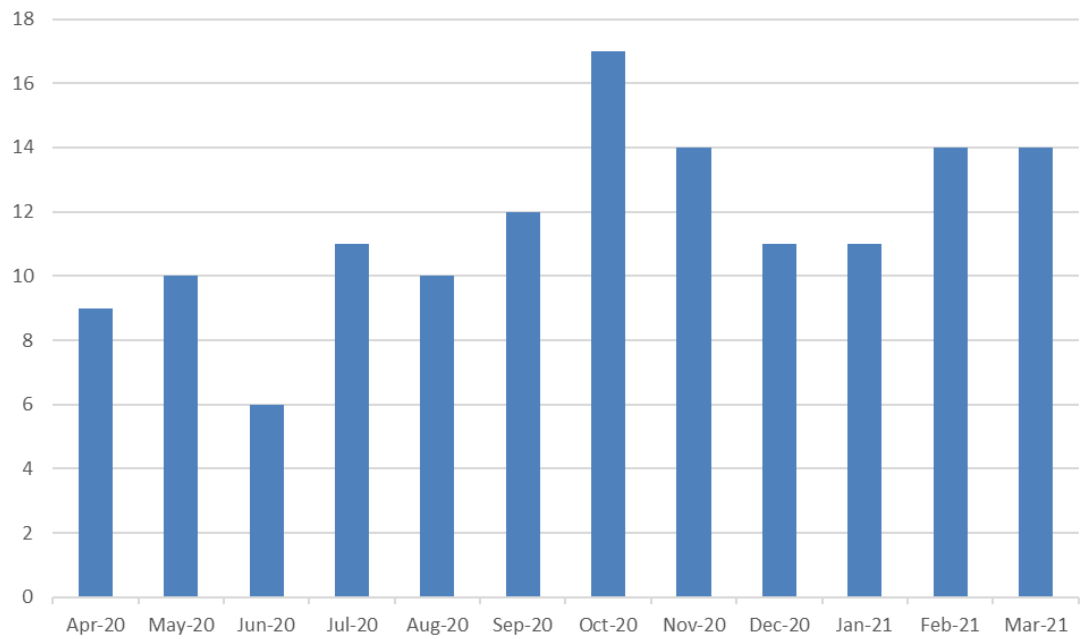


	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	Jan-21	Feb-21	Mar-21
ATIMP Trials	4	0	1	4	3	2	4	5	8	9	6	2

* This data also includes applications submitted through the Combined Ways of Working (CWoW) process.

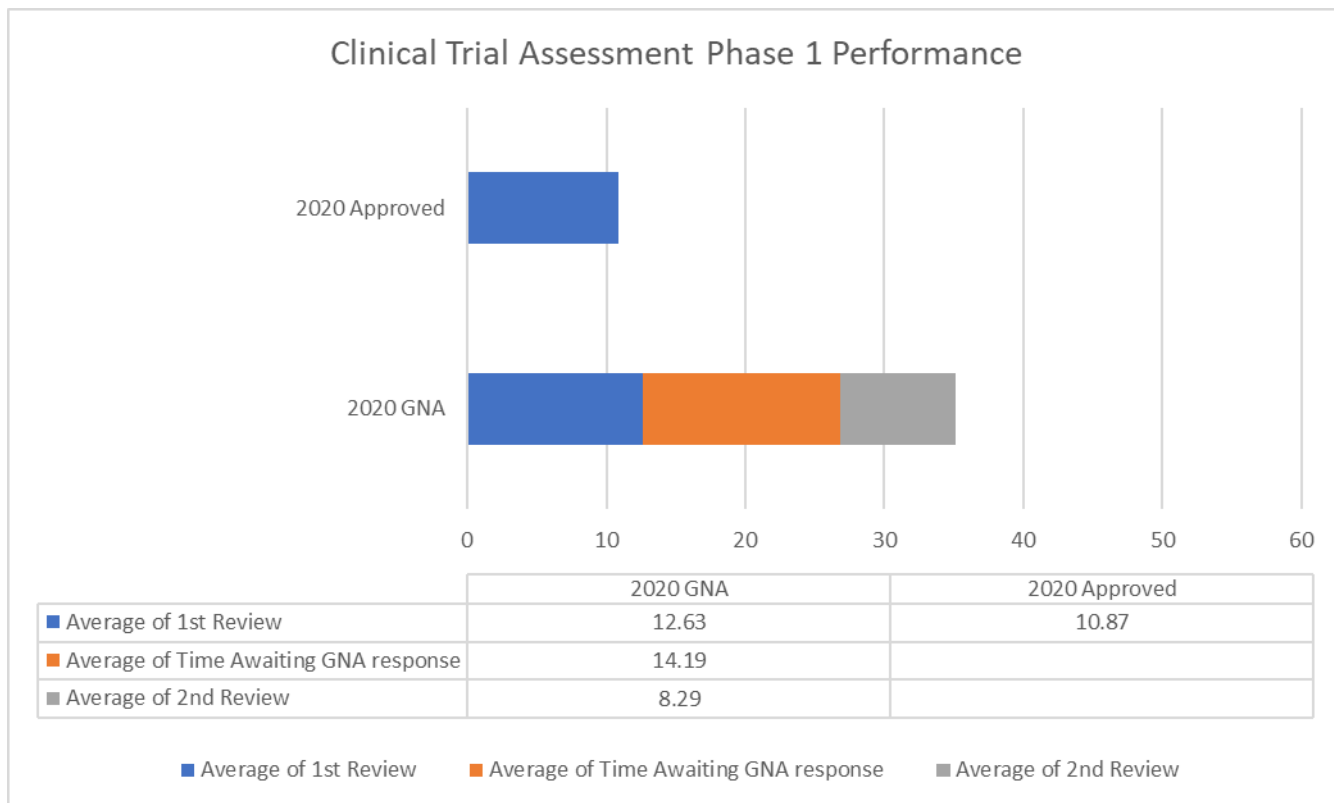
*This data reflects initial trial submissions including an advanced therapy investigational medicinal product (ATIMP). It does not reflect ATIMPs added to ongoing trials as a substantial amendment.

Number of Combined Ways of Working (CWoW) Applications Assessed



	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	Jan-21	Feb-21	Mar-21
■ Number of CWoW studies	9	10	6	11	10	12	17	14	11	11	14	14

	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	Jan-21	Feb-21	Mar-21
Number of CWoW studies	9	10	6	11	10	12	17	14	11	11	14	14



	2020 GNA raised	2020 No GNA raised
Average time for 1st Review	12.63	10.87
Average time awaiting GNA response from sponsor	14.19	-
Average time for 2nd Review	8.29	-

*Time is shown in days.

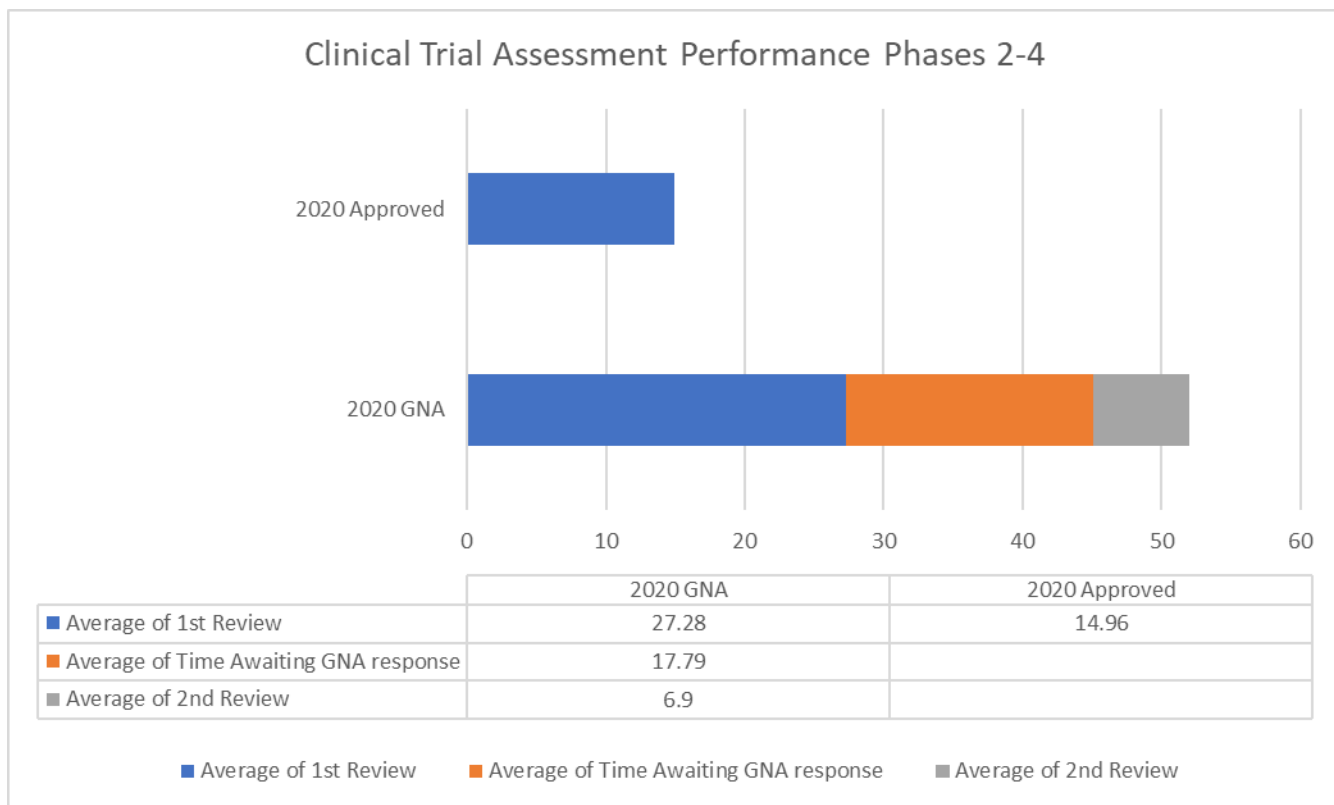
*This data represents a rolling average of applications determined in the financial year of 1st April 2020 – 31st March 2021 (inclusive).

* The data includes Phase 1 trials in Healthy Volunteer eligible for expedited review (average 14-days for initial assessment versus statutory timeframe of 30 days for initial assessment and 60 days for final decision).

*This data includes VHP national submissions and COVID-19 trials.

* This data does not include applications submitted through the Combined Ways of Working (CWoW) process.

(GNA = Grounds for non-acceptance)



	2020 GNA raised	2020 no GNA raised
Average time for 1st Review	27.28	14.96
Average time awaiting GNA response from sponsor	17.79	-
Average time for 2nd Review	6.90	-

*Time is shown in days.

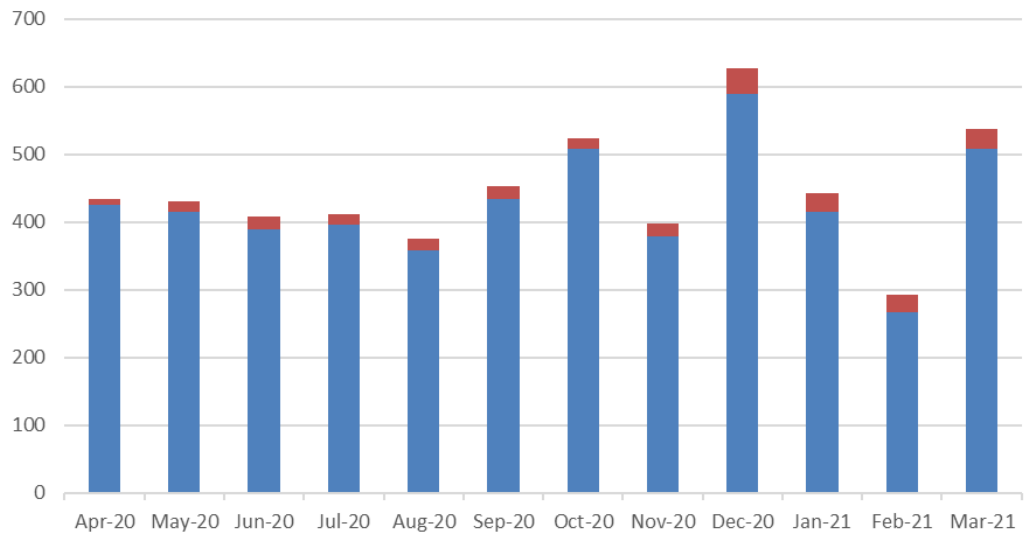
*This data represents a rolling average of applications determined in the financial year of 1st April 2020 – 31st March 2021 (inclusive).

*This data includes VHP national submissions and COVID-19 trials.

* This data does not include applications submitted through the Combined Ways of Working (CWoW) process.

(GNA = Grounds for non-acceptance)

All Substantial Amendments Assessed



	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	Jan-21	Feb-21	Mar-21
■ Substantial Amendments Submitted through CWoW Process	8	15	19	14	16	19	14	19	38	28	25	30
■ Standard Substantial Amendments	426	415	390	397	359	434	509	379	589	415	267	508

■ Standard Substantial Amendments ■ Substantial Amendments Submitted through CWoW Process

	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	Jan-21	Feb-21	Mar-21
Standard Substantial Amendments	426	415	390	397	359	434	509	379	589	415	267	508
Substantial Amendments Submitted through CWoW Process	8	15	19	14	16	19	14	19	38	28	25	30
Total	434	430	409	411	375	453	523	398	627	443	292	538

(CWoW = Combined Ways of Working)