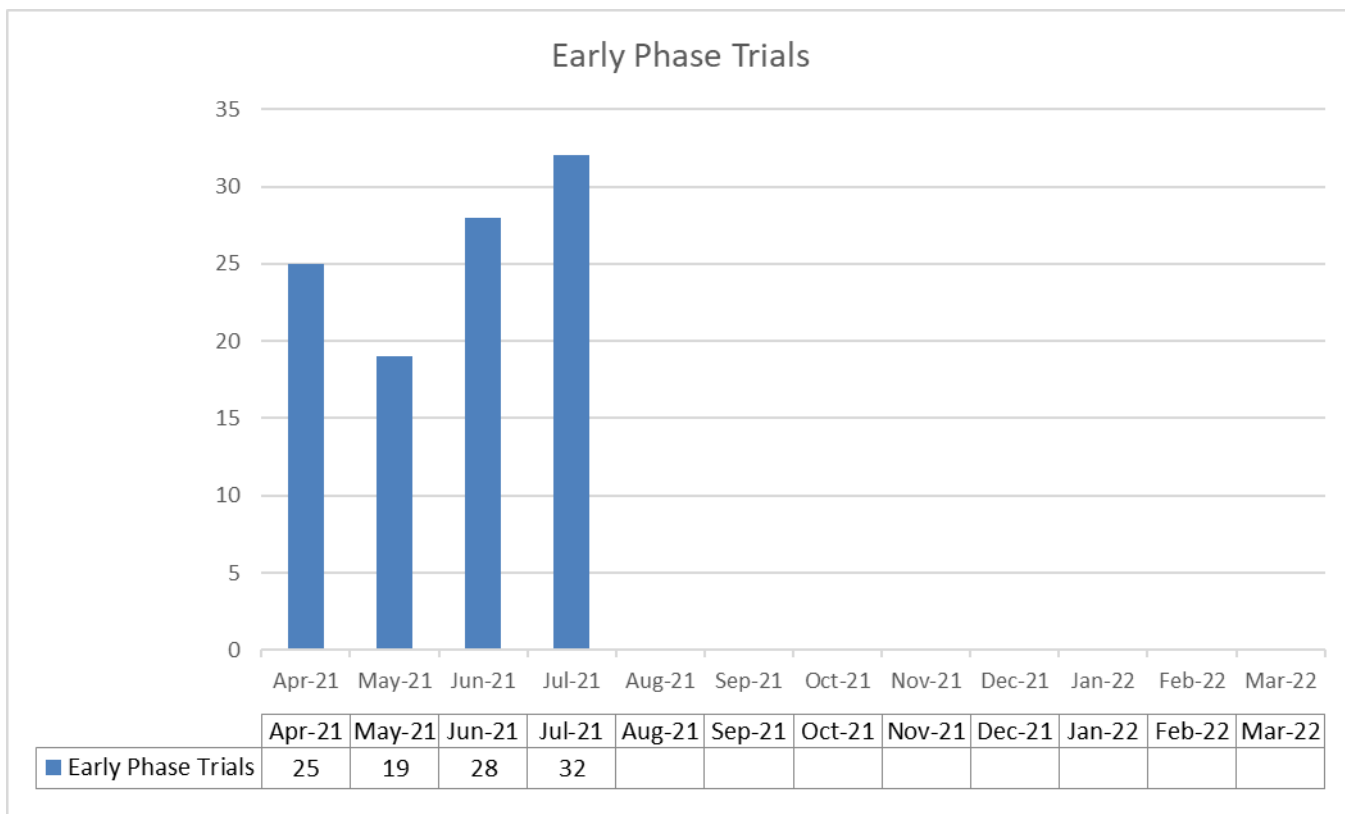


	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22	Feb-22	Mar-22
Number of FTIH studies	15	7	10	11								

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

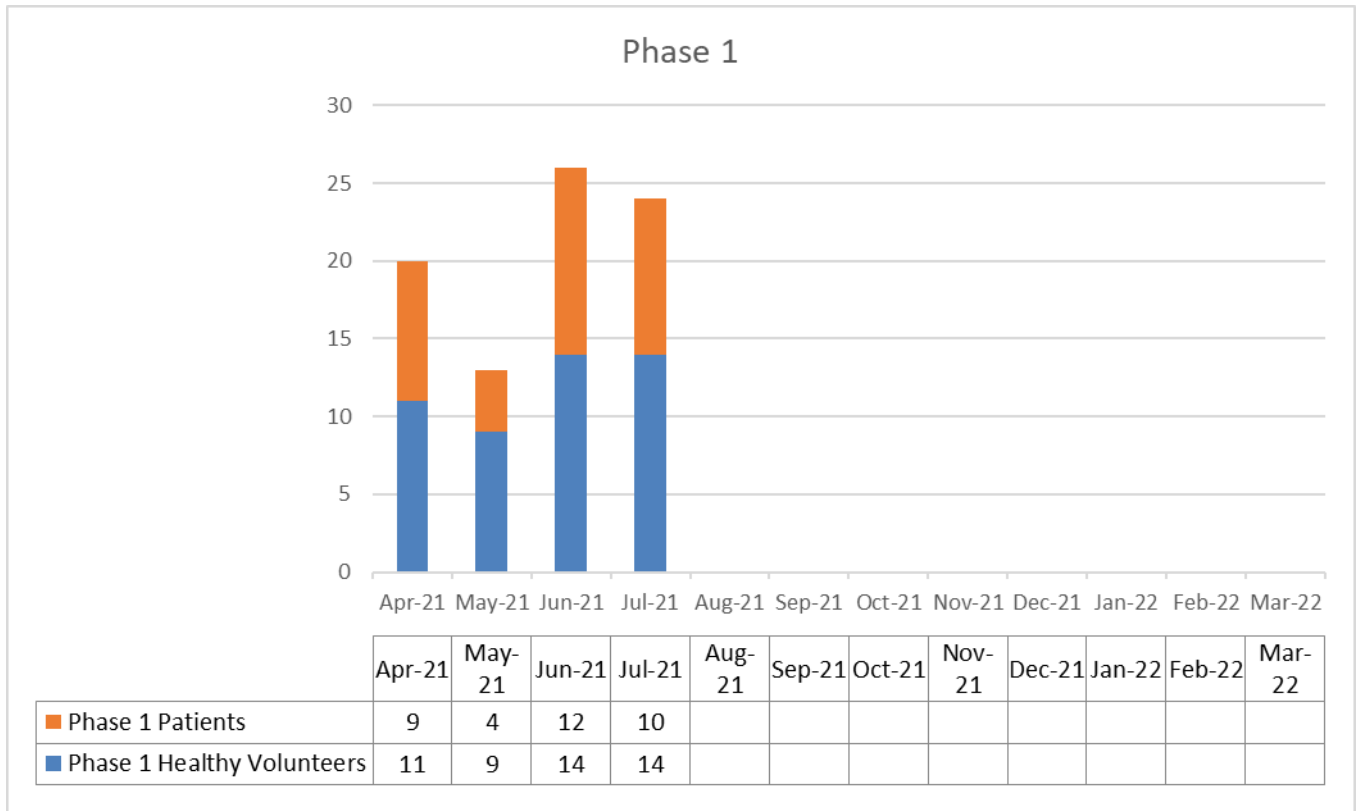
(FIH= First In Human)



	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								

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

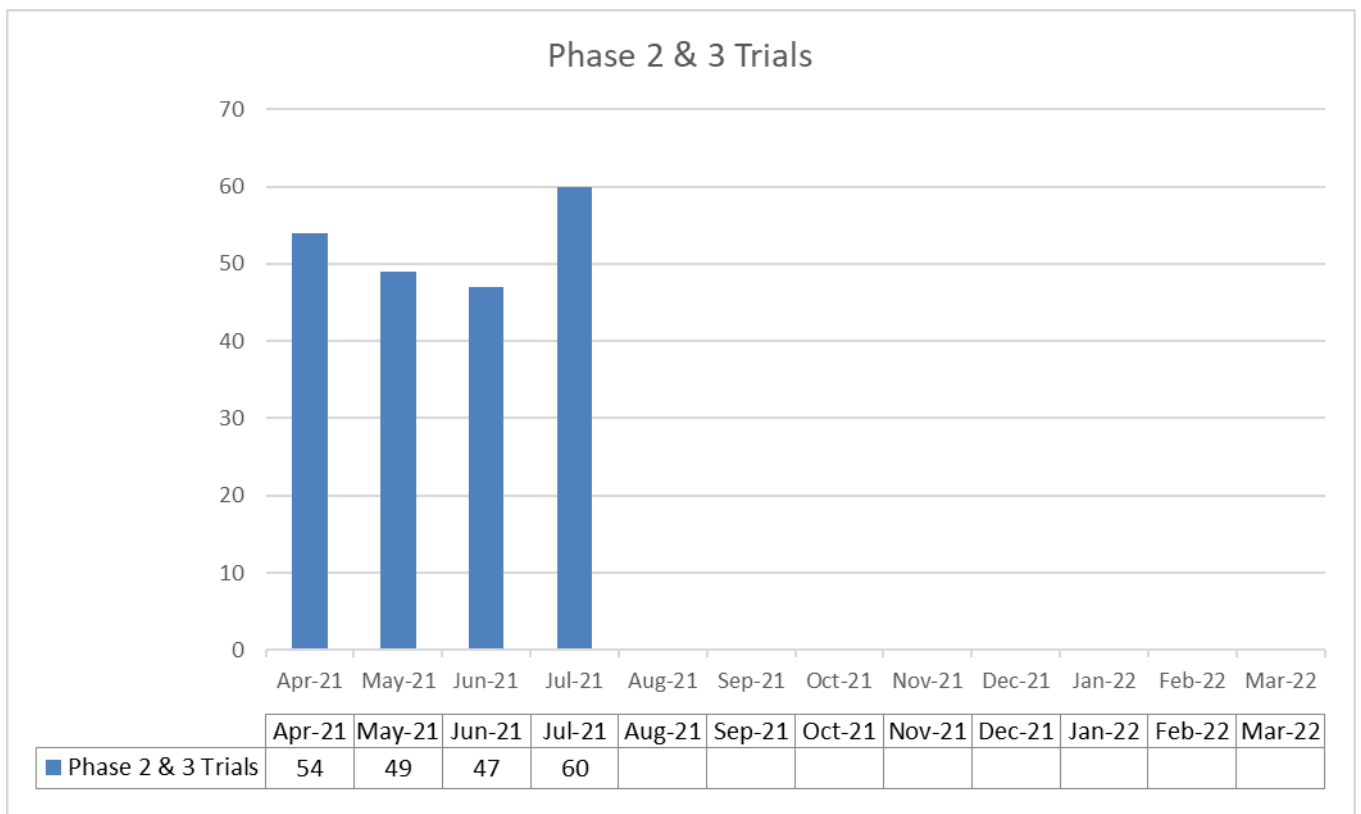
* This data represents clinical trials where the Sponsor has declared a Phase 1 element (e.g. Phase 1/2 trials).



	Apr-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								
Phase 1 Patients	9	4	12	10								
Total	20	13	26	24								

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

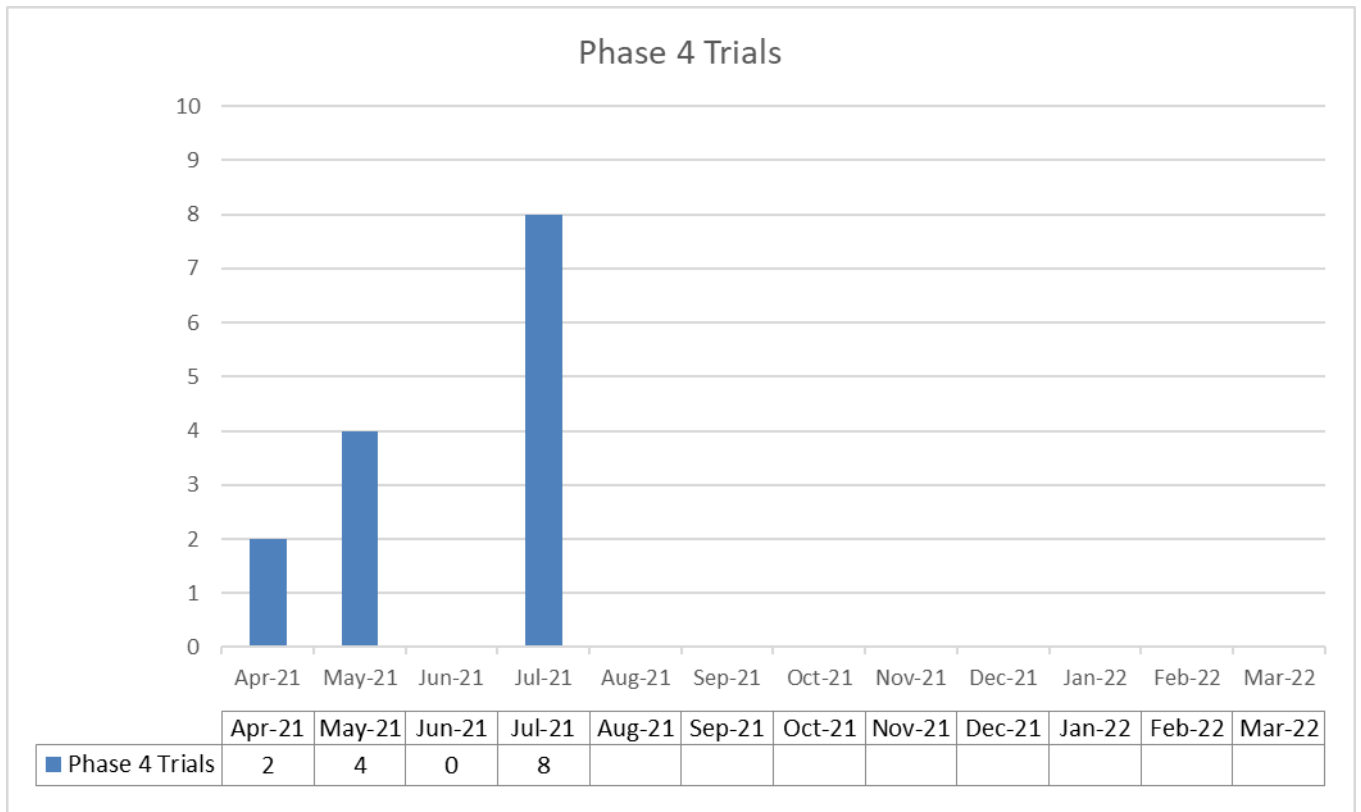
* This data represents clinical trials the Sponsor has declared as Phase 1 only.



	Apr-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								

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

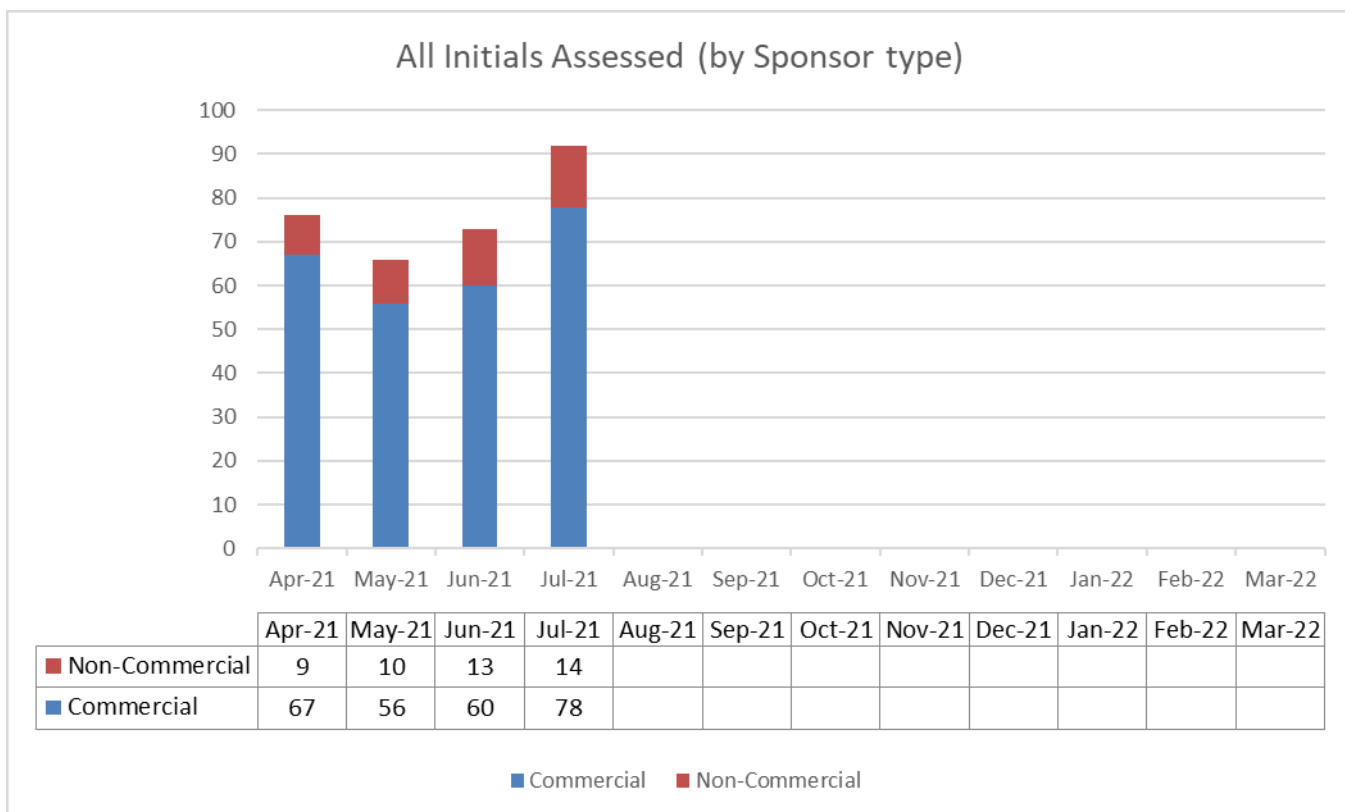
* This data represents clinical trials where the Sponsor has declared a Phase 2 or 3 element.



	Apr-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								

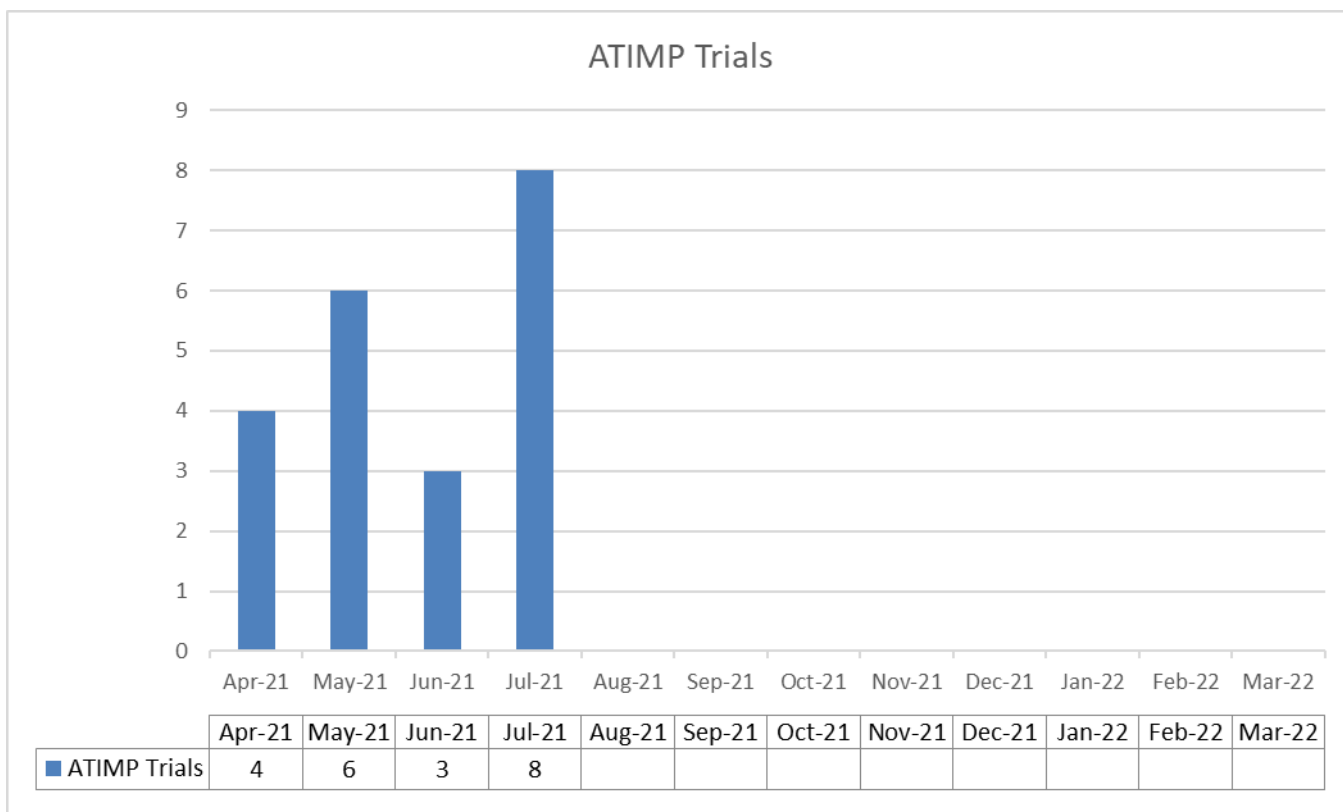
* This data also includes applications submitted through the Combined Ways of Working (CWoW) process.

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



	Apr-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								
Non-Commercial	9	10	13	14								
Total	76	66	73	92								

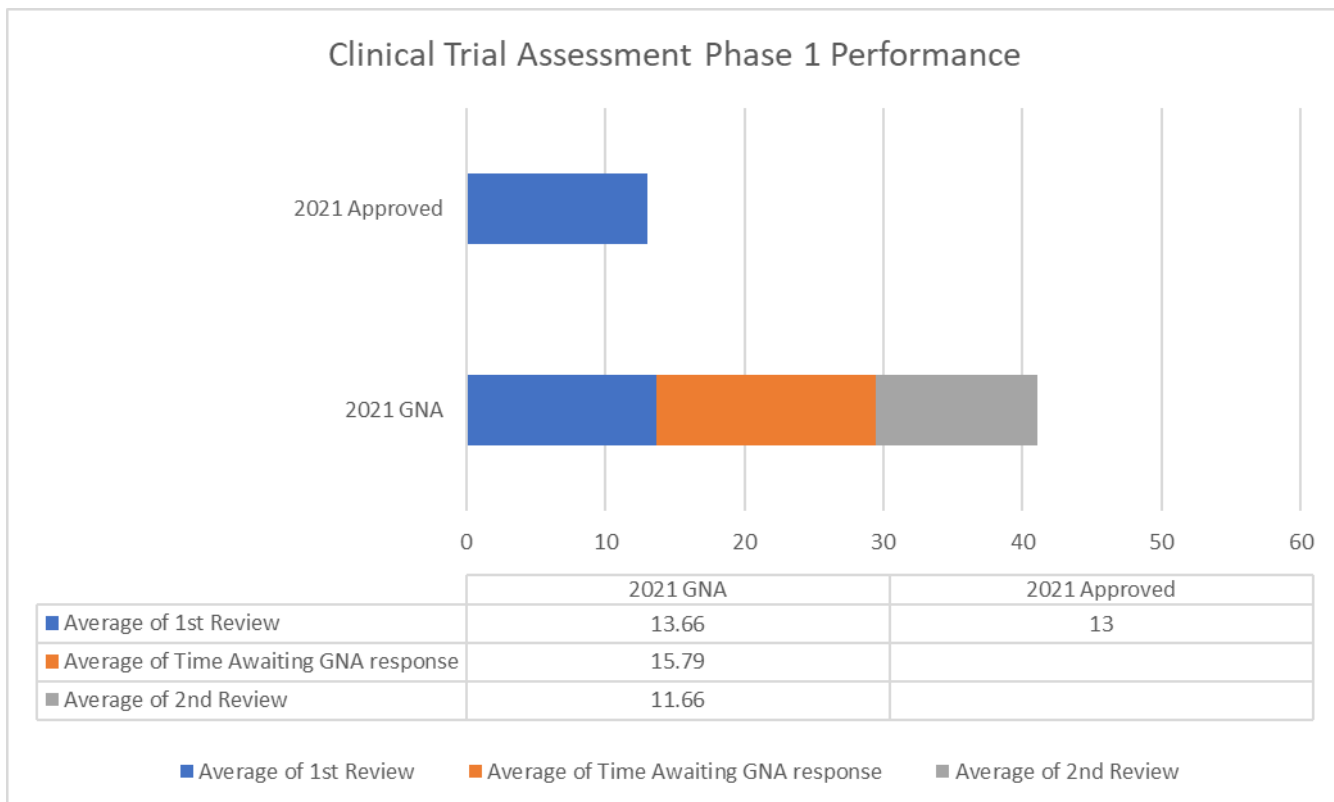
* This data also includes applications submitted through the Combined Ways of Working (CWoW) process.



	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								

* 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.



	2021 GNA	2021 Approved
Average time for 1st Review	13.66	13.0
Average time awaiting GNA response from sponsor	15.79	-
Average time for 2nd Review	11.66	-

*Time is shown in days.

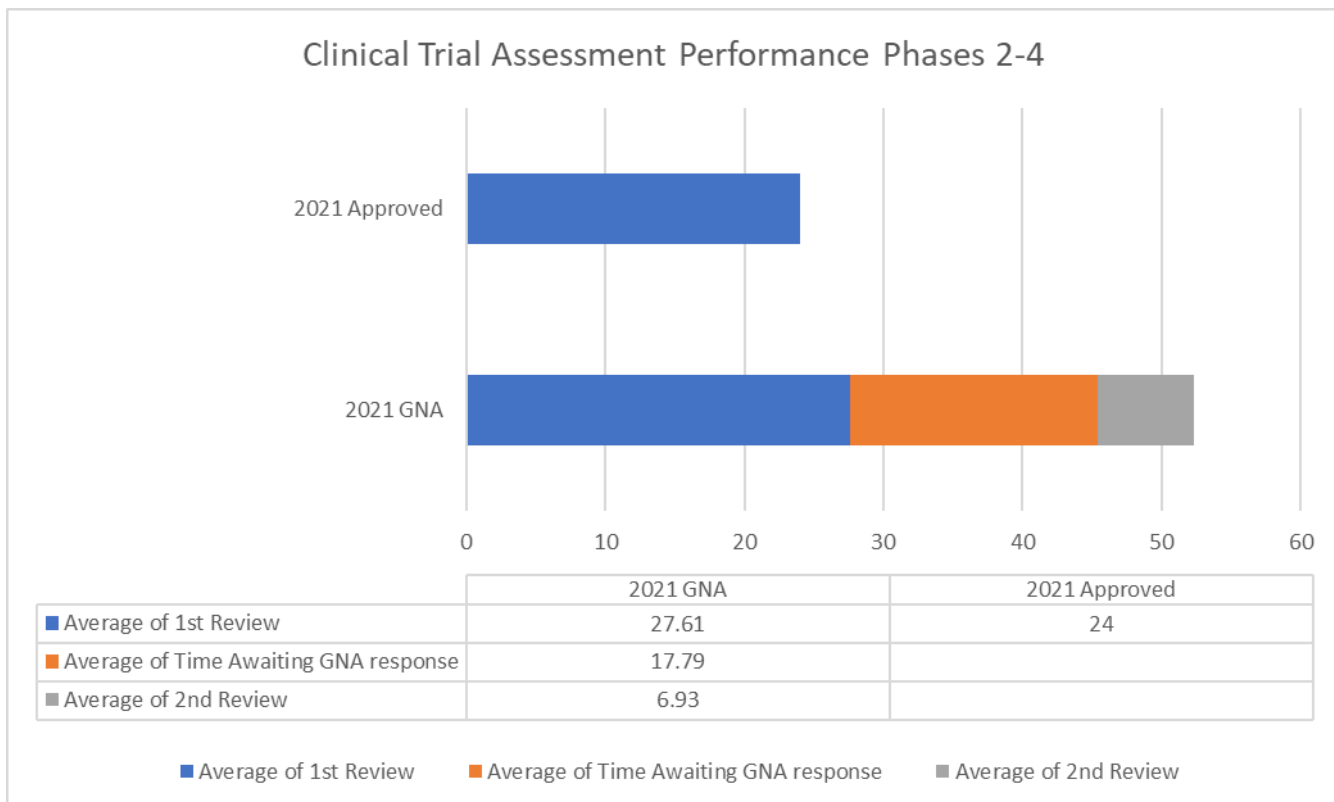
*This data represents a rolling average of applications determined in the financial year of 1st April 2021 – 31st March 2022 (inclusive).

* 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 Ways of Working (CWoW) process.

(GNA = Grounds for non-acceptance)



	2021 GNA	2021 Approved
Average time for 1st Review	27.61	24.0
Average time awaiting GNA response from sponsor	17.79	-
Average time for 2nd Review	6.93	-

*Time is shown in days.

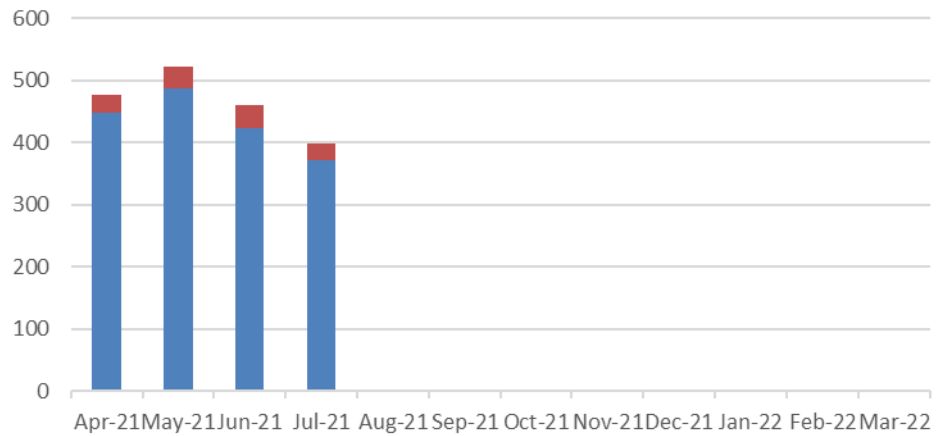
*This data represents a rolling average of applications determined in the financial year of 1st April 2021 – 31st March 2022 (inclusive).

*This data includes COVID-19 trials.

* This data does not include applications submitted through the Combined Ways of Working (CWoW) 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 CWoW Process	29	35	37	26								
■ Standard Substantial Amendments	448	488	423	372								

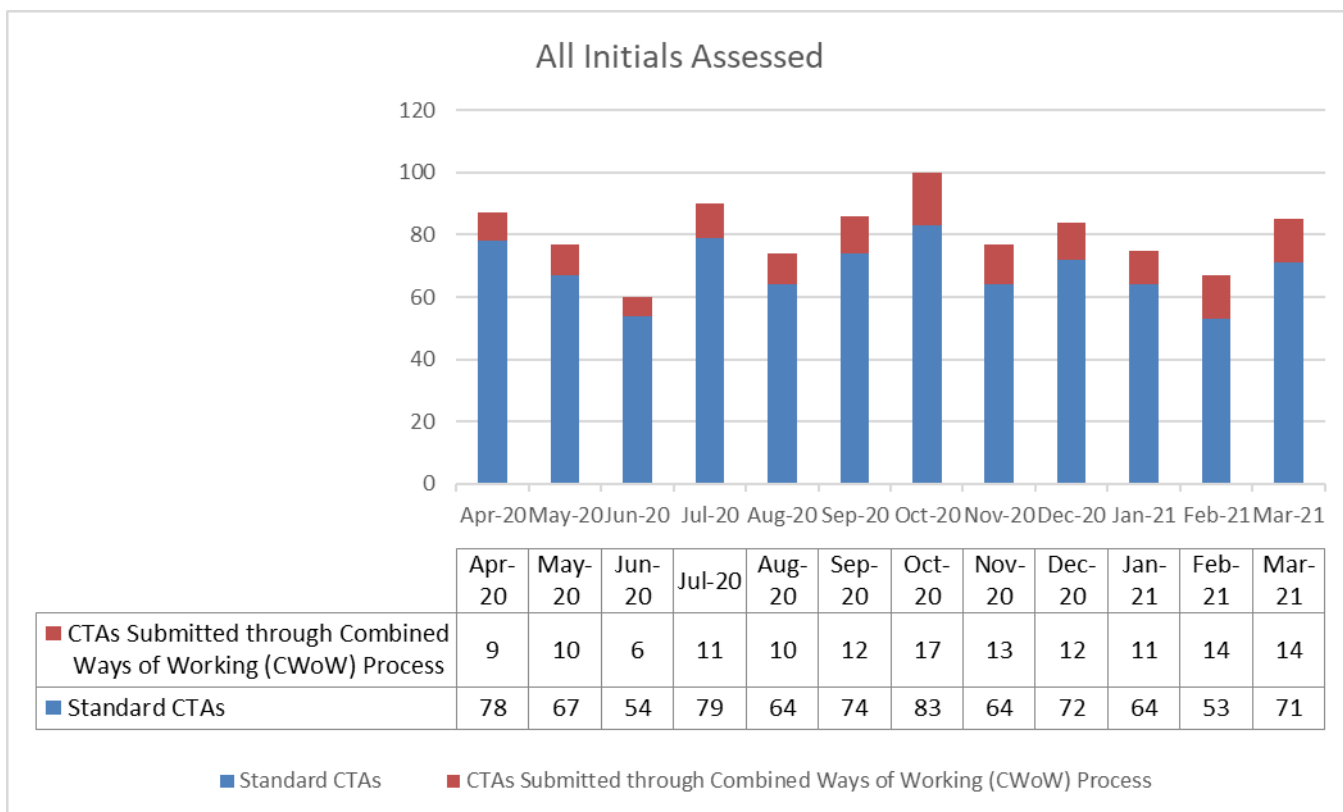
■ Standard Substantial Amendments ■ Substantial Amendments Submitted through CWoW Process

	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22	Feb-22	Mar-22
Standard Substantial Amendments	448	488	423	372								
Substantial Amendments Submitted through CWoW Process	29	35	37	26								
Total	477	523	460	398								

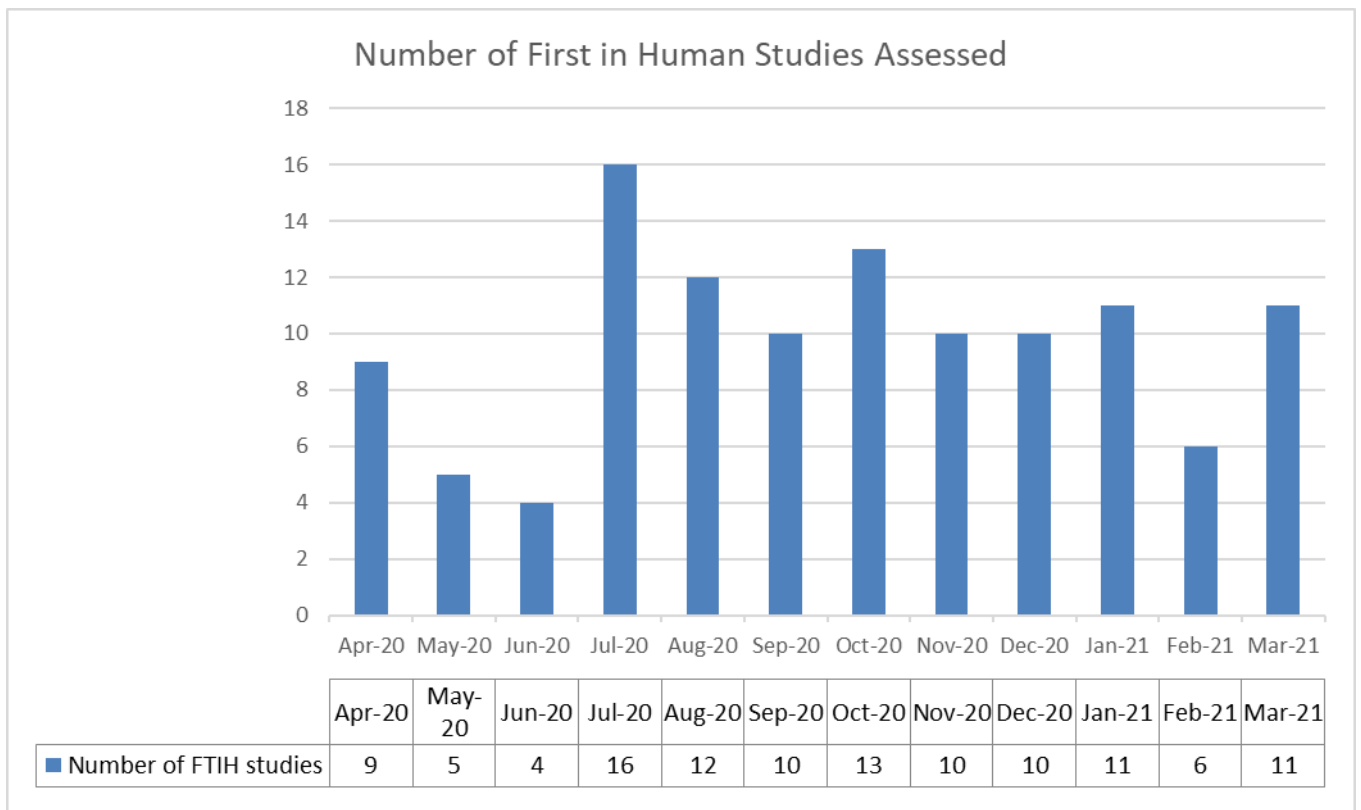
(CWoW = Combined Ways of Working)

Annex 1 – Data for financial year 2020-2021

Clinical trials for medicines: authorisation assessment performance



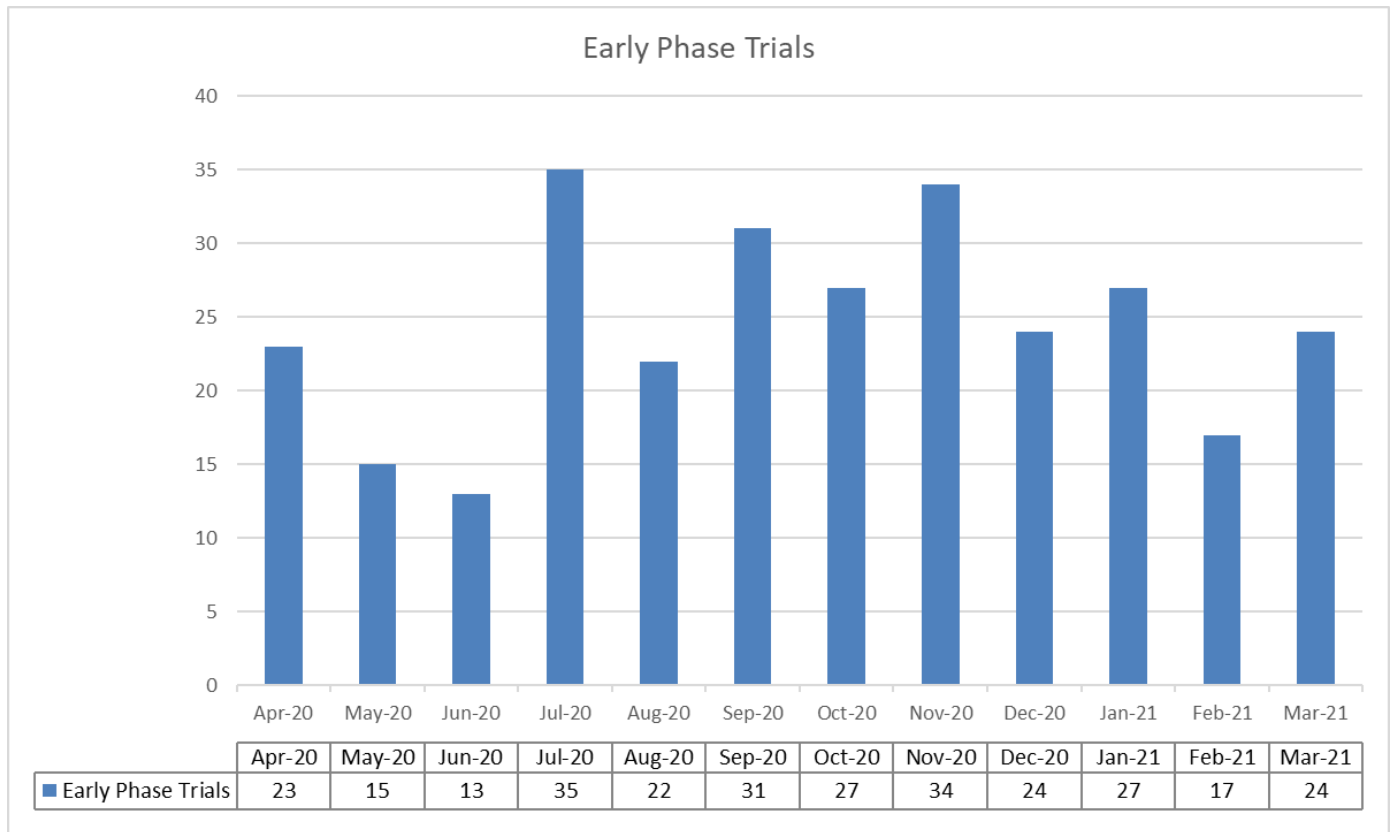
	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	Jan-21	Feb-21	Mar-21
Standard CTAs	78	67	54	79	64	74	83	64	72	64	53	71
CTAs Submitted through Combined Ways of Working (CWoW) Process	9	10	6	11	10	12	17	13	12	11	14	14
Total	87	77	60	90	74	86	100	77	84	75	67	85



	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.

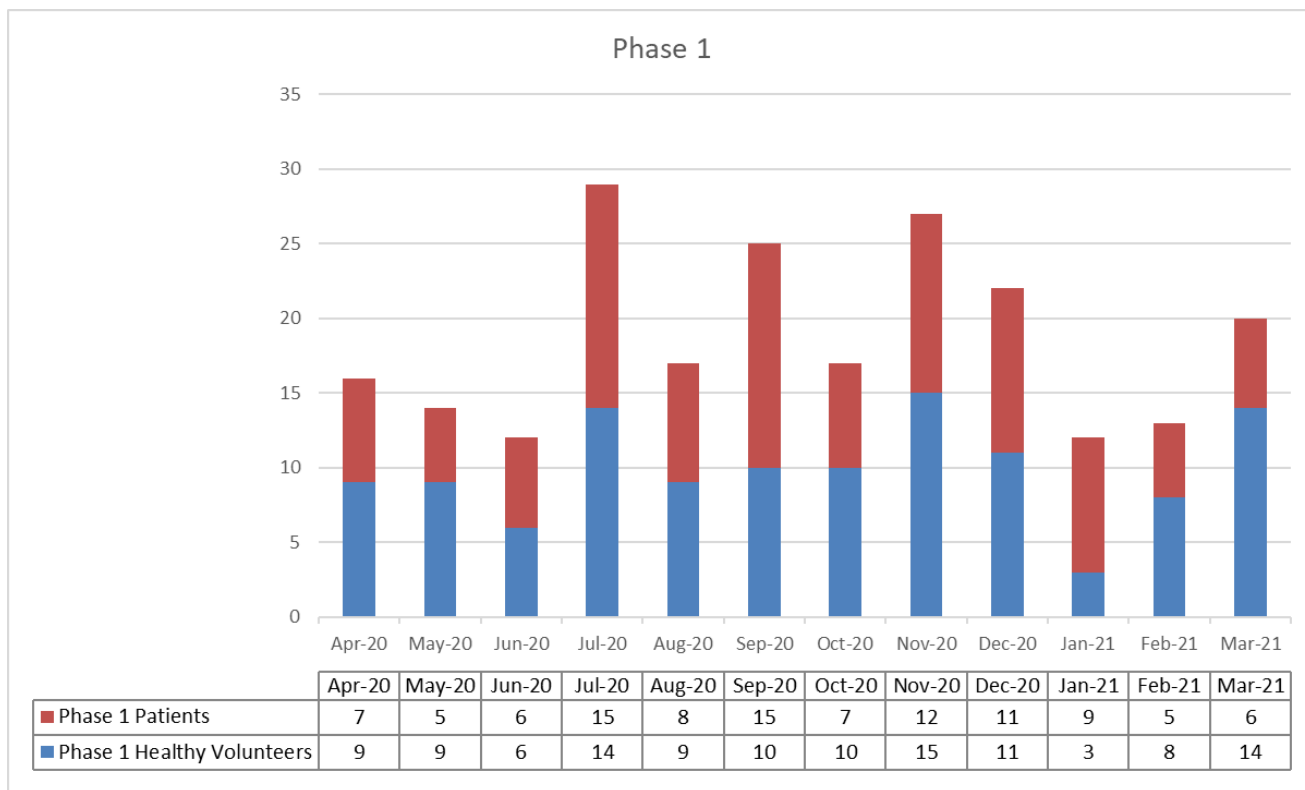
(FIH= First In Human)



	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.

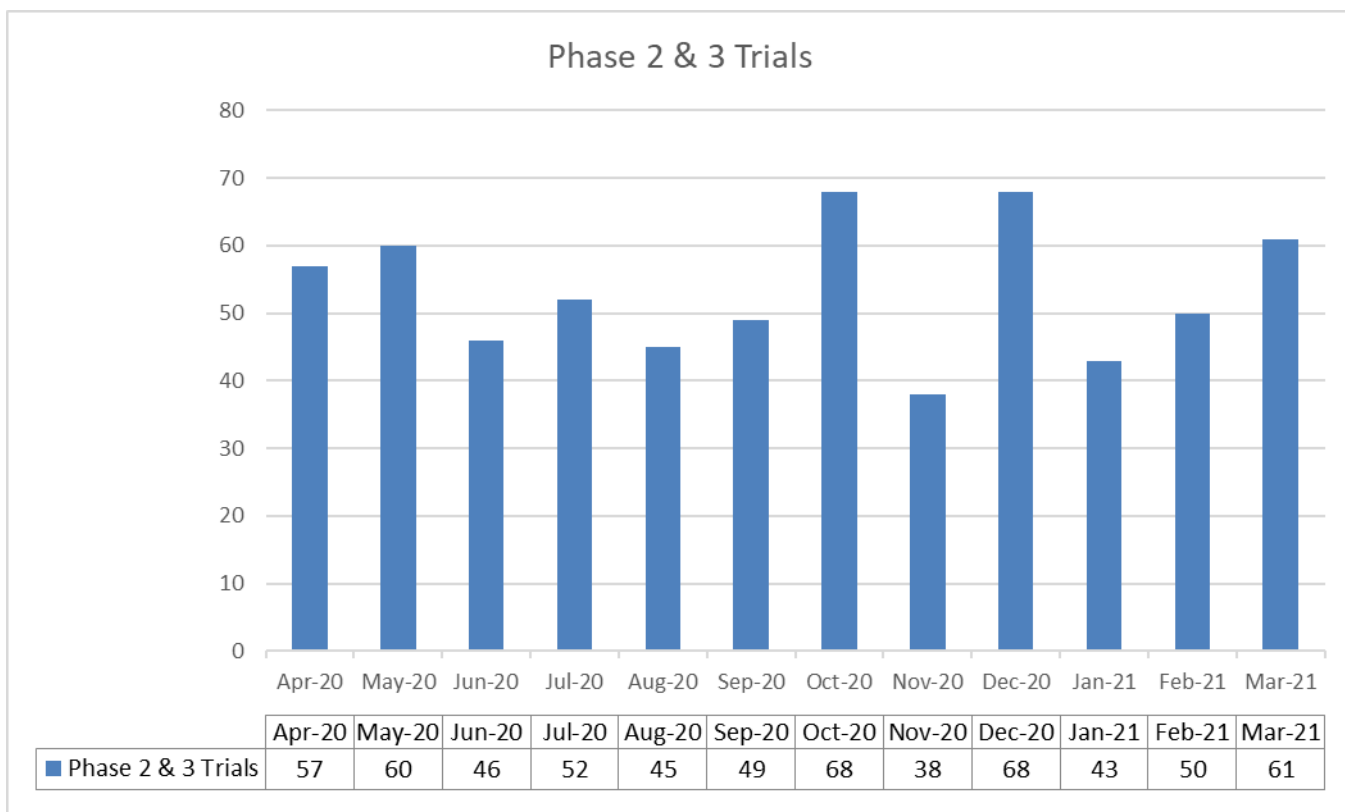
* This data represents clinical trials where the Sponsor has declared a Phase 1 element (e.g. Phase 1/2 trials).



	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.

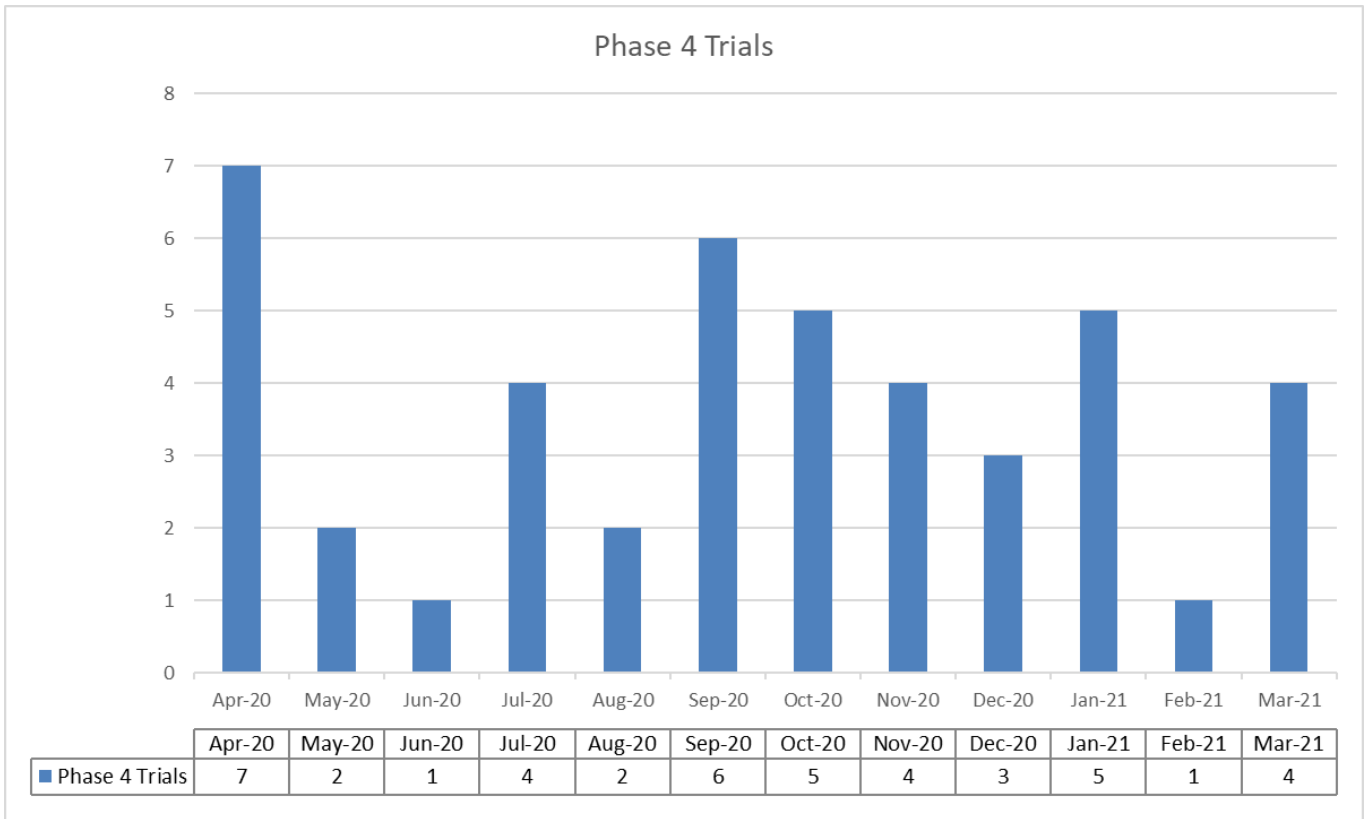
* This data represents clinical trials the Sponsor has declared as Phase 1 only.



	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.

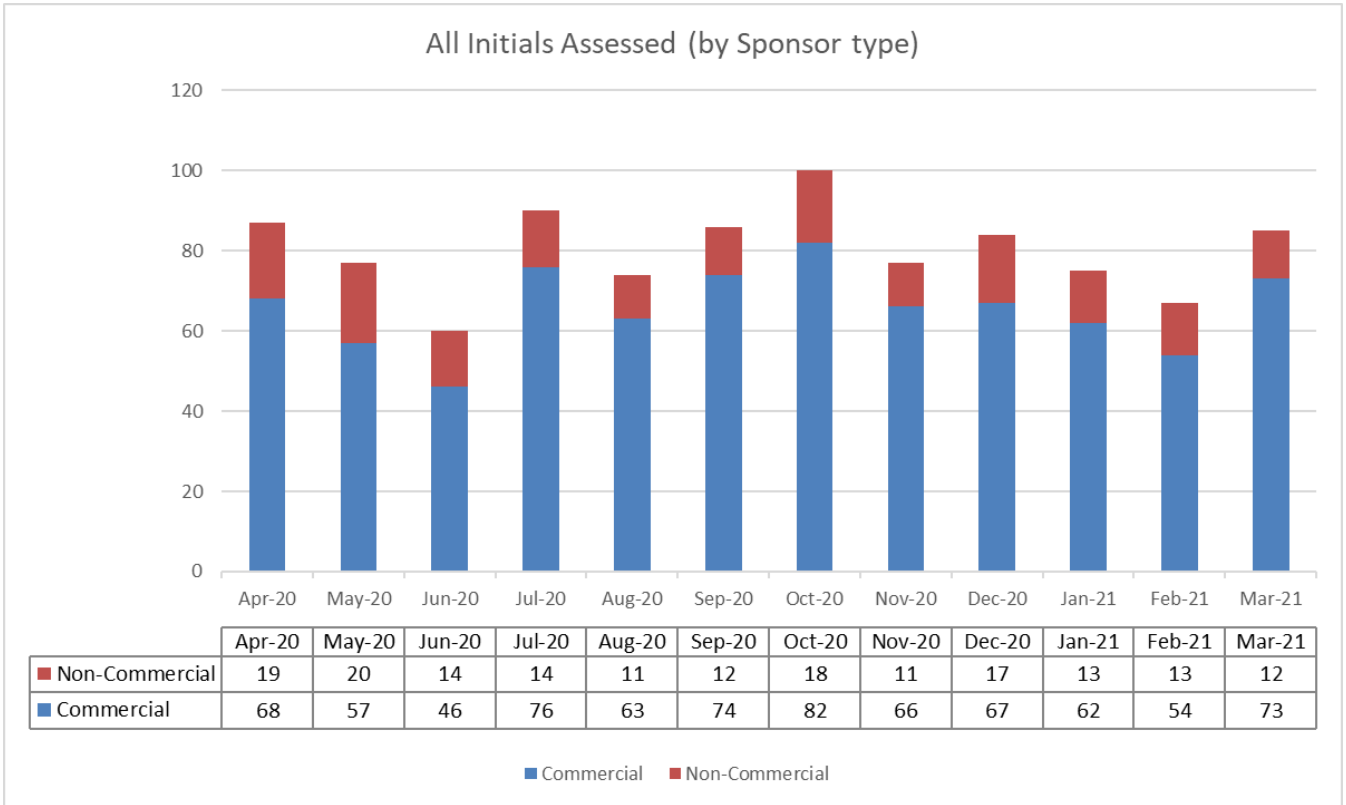
* This data represents clinical trials where the Sponsor has declared a Phase 2 or 3 element.



	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

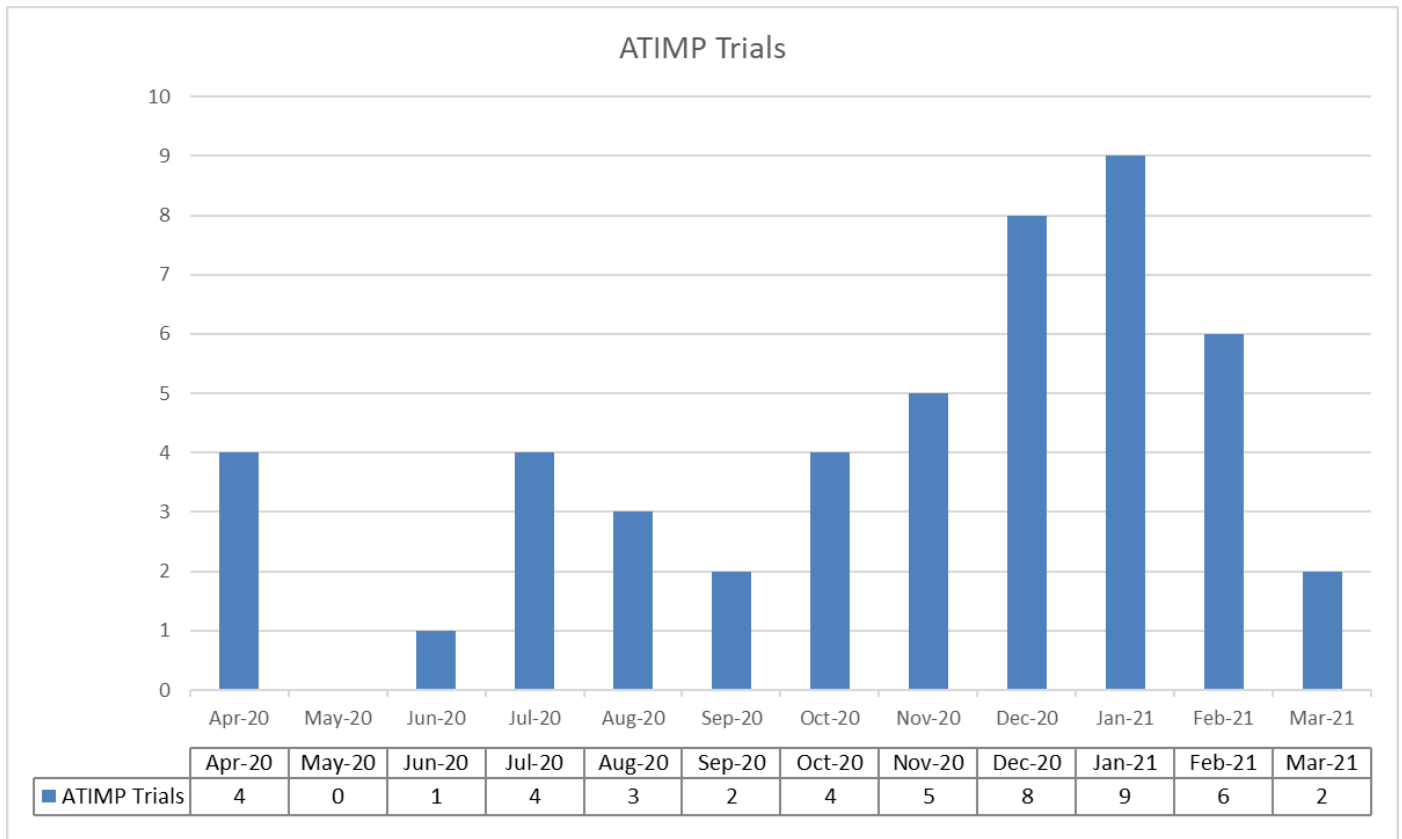
* This data also includes applications submitted through the Combined Ways of Working (CWoW) process.

* 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.

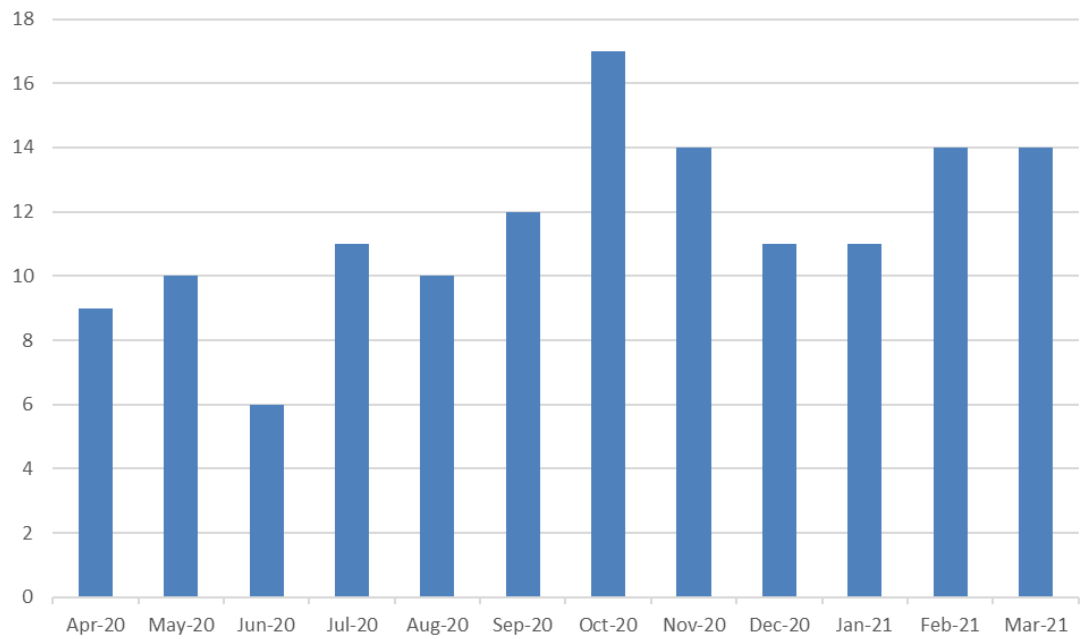


	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	Jan-21	Feb-21	Mar-21
ATIMP Trials	4	0	1	4	3	2	4	5	8	9	6	2

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

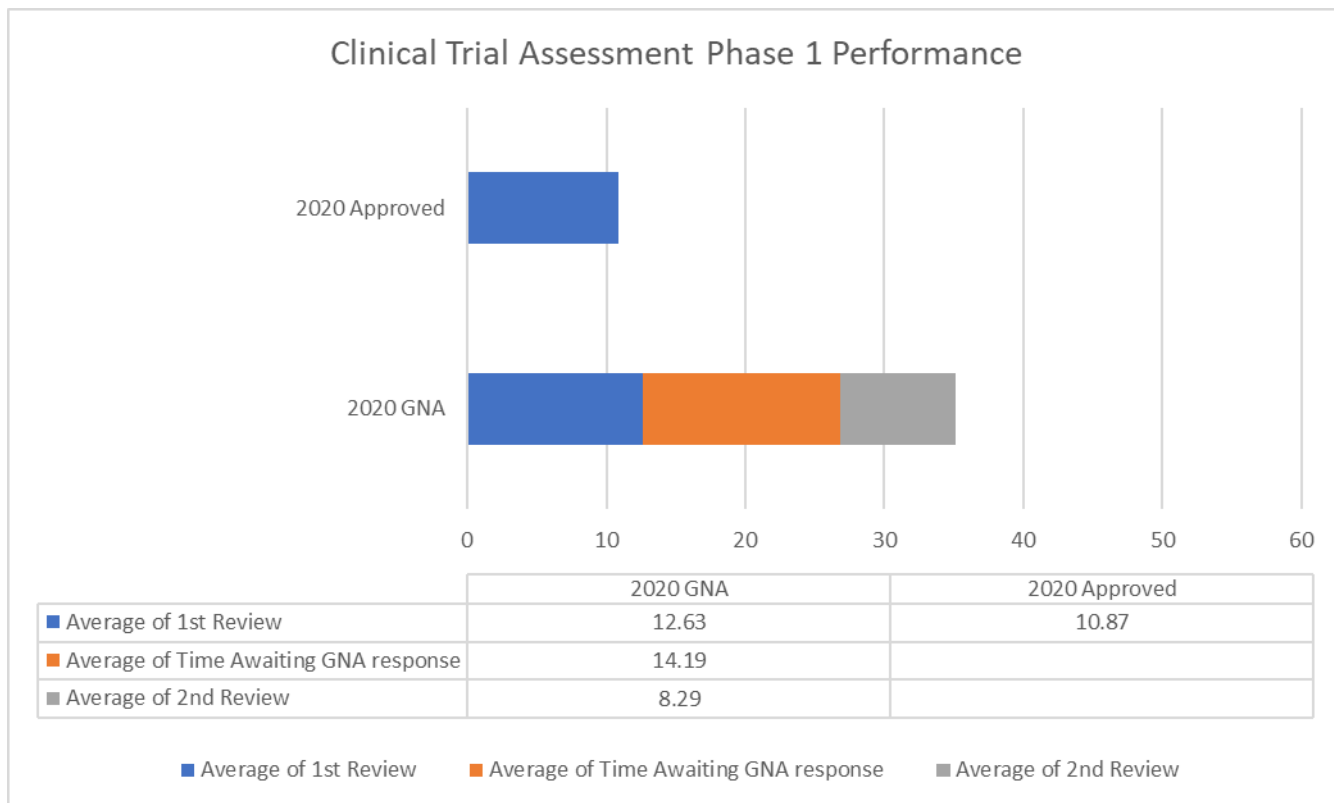
*This data reflects initial trial submissions including an advanced therapy investigational medicinal product (ATIMP). It does not reflect ATIMPs added to ongoing trials as a substantial amendment.

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.

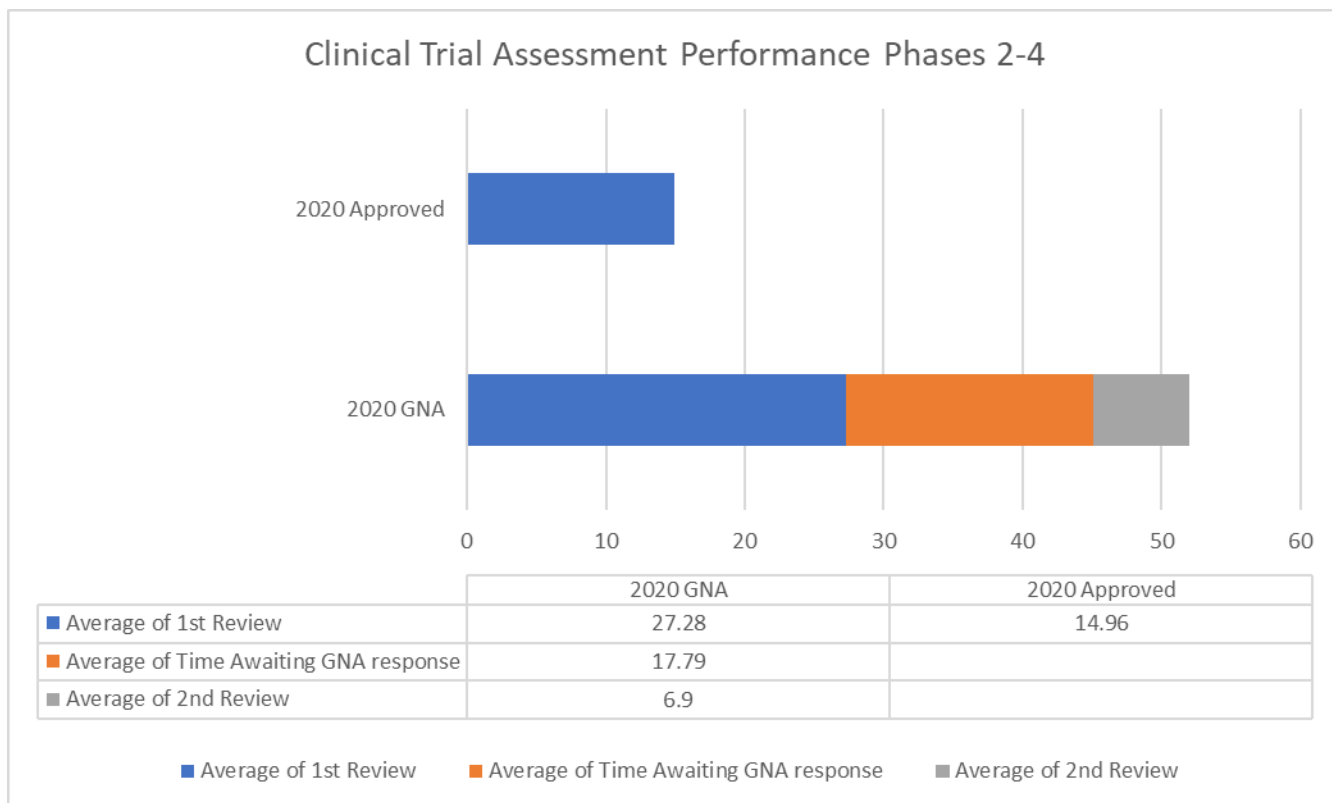
*This data represents a rolling average of applications determined in the financial year of 1st April 2020 – 31st March 2021 (inclusive).

* 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.

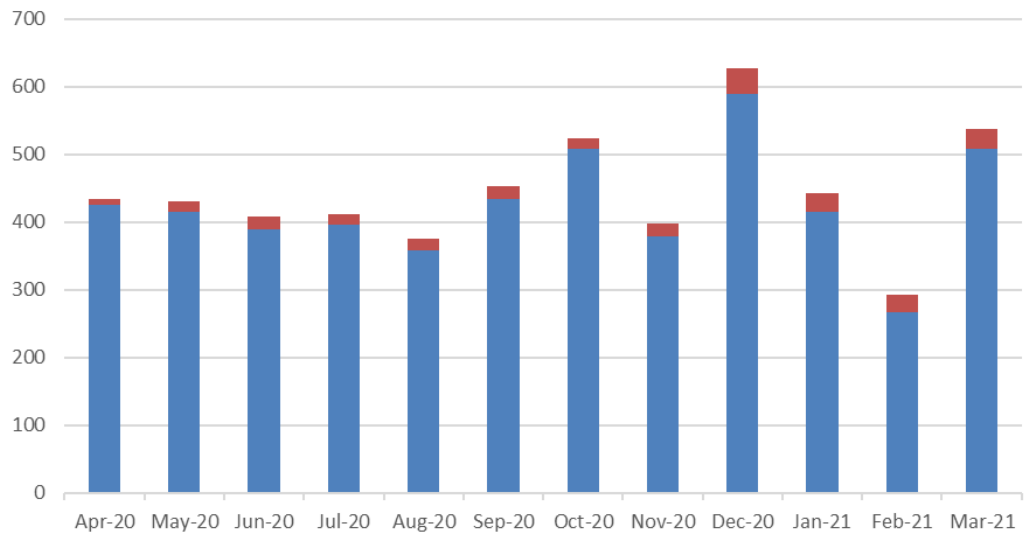
*This data represents a rolling average of applications determined in the financial year of 1st April 2020 – 31st March 2021 (inclusive).

*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)