



4<sup>th</sup> EUFEMED CONFERENCE

# Studies in healthy volunteers

Evolution in recruitment of healthy volunteers, before, during and after the pandemic

# Pandemic and clinical trials

## Publications

A key limitation of the present report is the possibility of a delay in the update of trial status on ClinicalTrials.gov; thus, these findings likely represent an underestimate of the true impact of the pandemic. In conclusion, the COVID-19 pandemic has had profound effects on active non-COVID-19 clinical trials. Long-term data will determine the full extent of the disruption the pandemic imposes on clinical research.

[1]

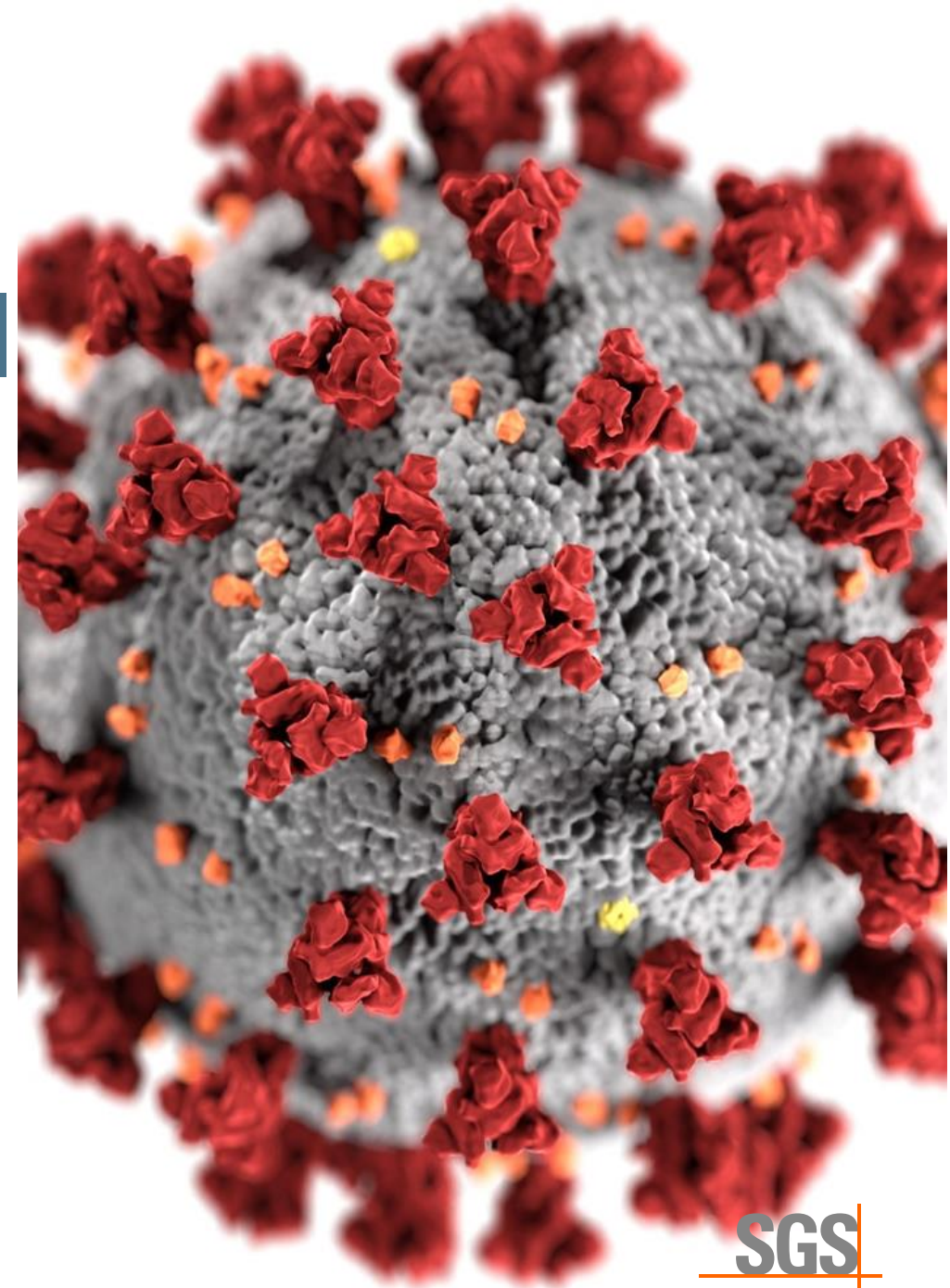
The drivers of choice to participate in a clinical trial could also be affected by the COVID-19 pandemic. During times of crisis people are more likely to show prosocial behavior,<sup>19</sup> which could positively affect recruitment for trials and potentially for interventions for COVID-19 risk groups. This is perhaps illustrated by the large number of people who, after announcements that challenge studies with SARS-CoV-2 could force a breakthrough in the development of vaccines,<sup>20,21</sup> volunteered for such trials even before the potential

[2]

immediately available to the public.

Regarding the number of clinical trial publications, we note that the least related group has been affected negatively, with the number of publications on clinical trials dropping by a staggering 24%. At the same time, publications on clinical trials for COVID-19-related MeSH have increased by a factor of 2.1. Note, however, that the effect on clinical trials is not significant in the continuous regression. The discrepancy across Tables 3 and 4 highlights that, especially for

[3]



# Number of early phase trials

Open data

## Overall trials

	2018	2019	2020	2021	2022
<b>Belgium</b> [4, 5]	56	69	74	75	59
<b>Germany</b> [6]	56	63	94	94	169
<b>UK</b> [7]	67	64	66	75	108
<b>Clinical trial.gov</b> [5]	30951	32515	36722	37018	38034

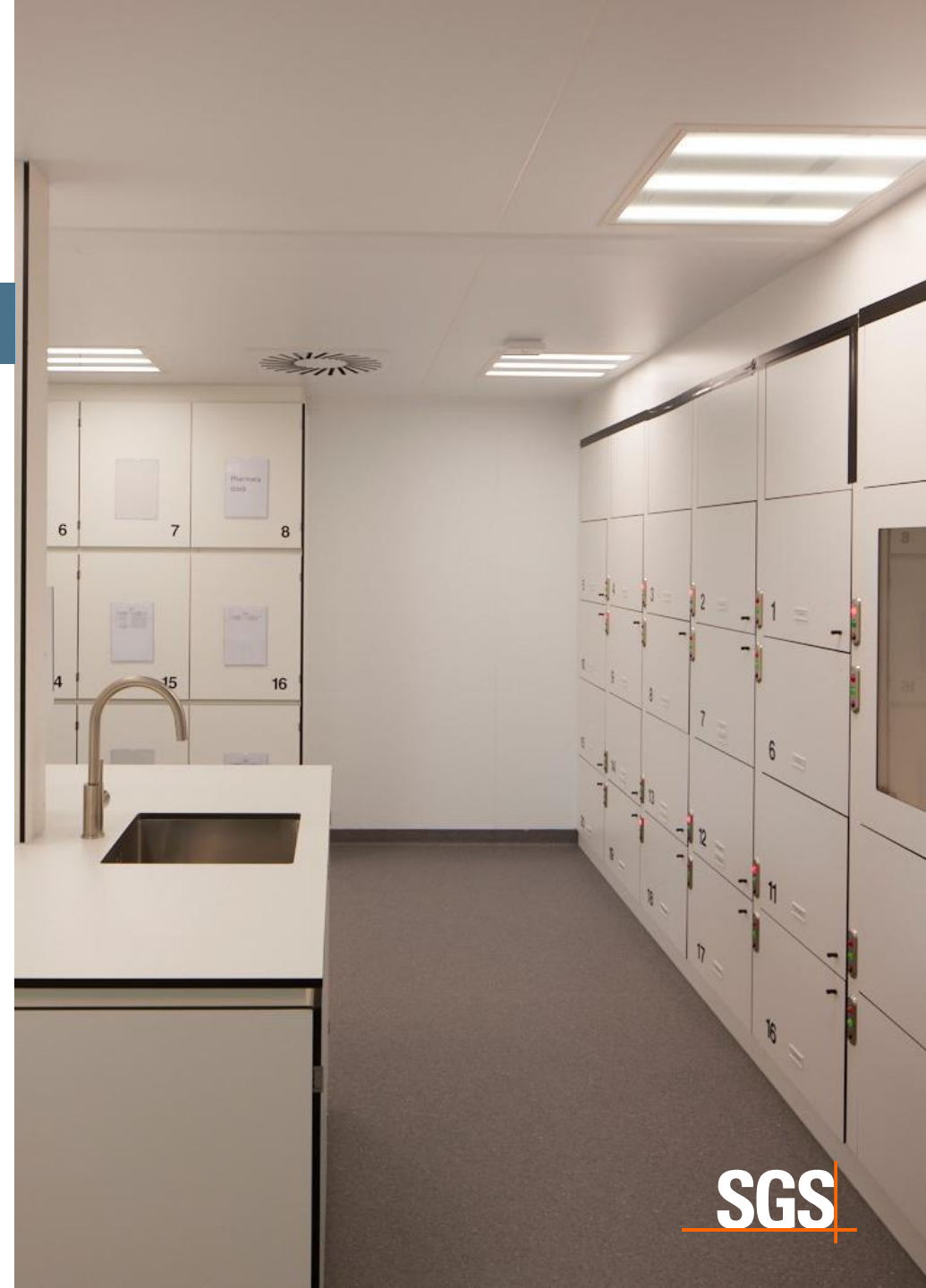


# Trial types at SGS

Data from SGS trials

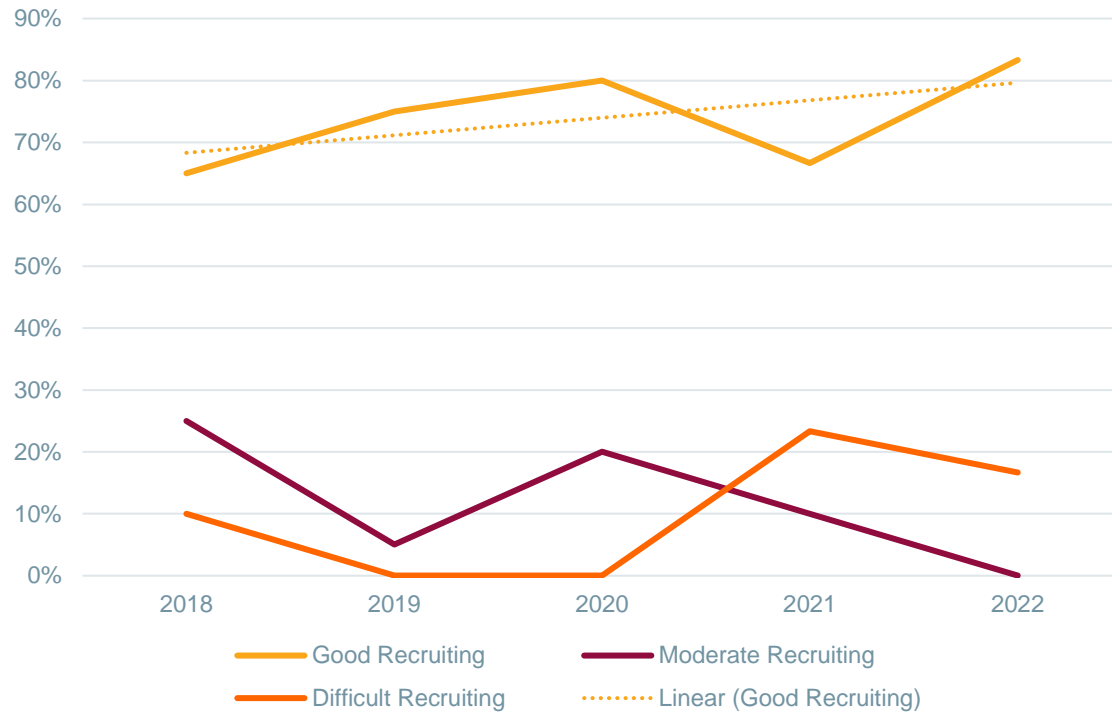
## Recruitment per year

	2018	2019	2020	2021	2022
<b>Fee median</b>	2370	3013	2464	2827	2428
<b>Duration Median</b>	57	29	31	43	44
<b>Inhouse Median</b>	5	8	5	5	4
<b>Good Recruiting</b>	65%	75%	80%	67%	83%
<b>Moderate Recruiting</b>	25%	5%	20%	10%	0%
<b>Difficult Recruiting</b>	10%	0%	0%	23%	17%

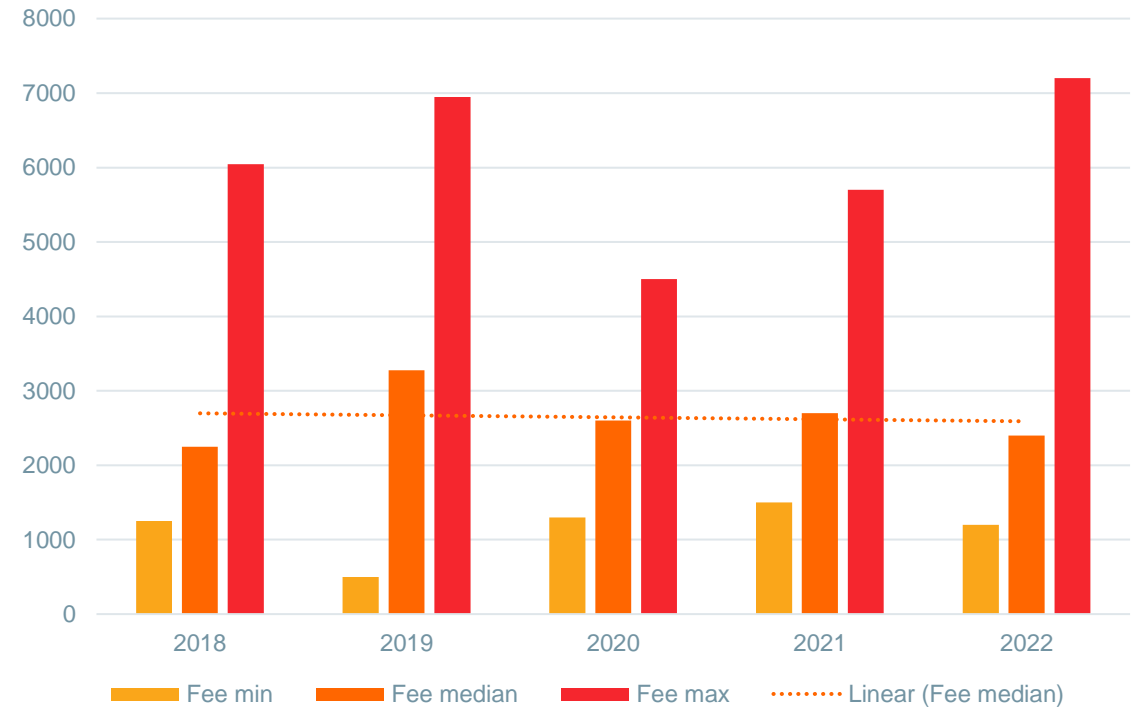


# Graphs from SGS trials

Recruitment on trials

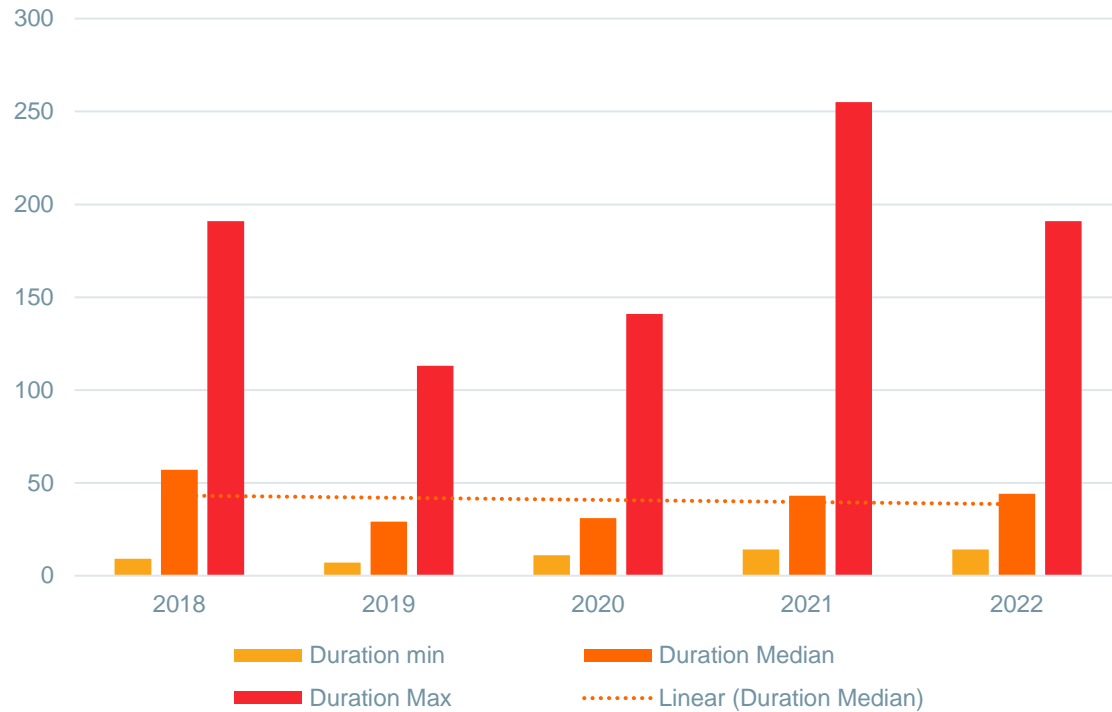


Fee

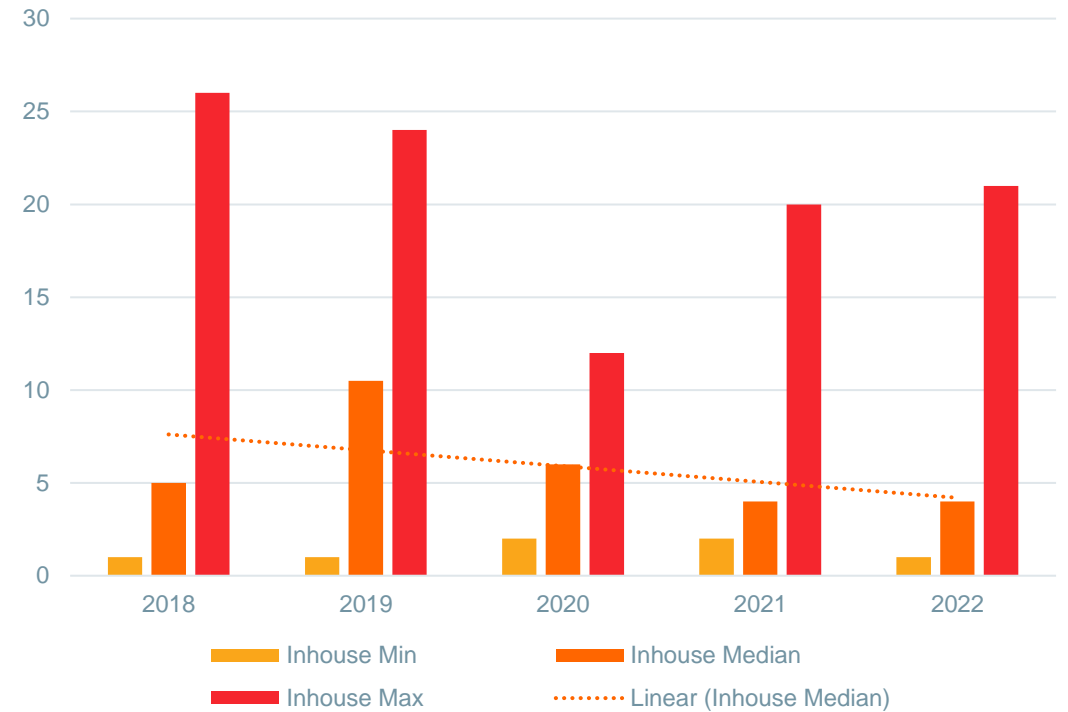


# Graphs from SGS trials

## Duration of trials



## Inhouse stay



# Trial types at SGS

Data from SGS trials

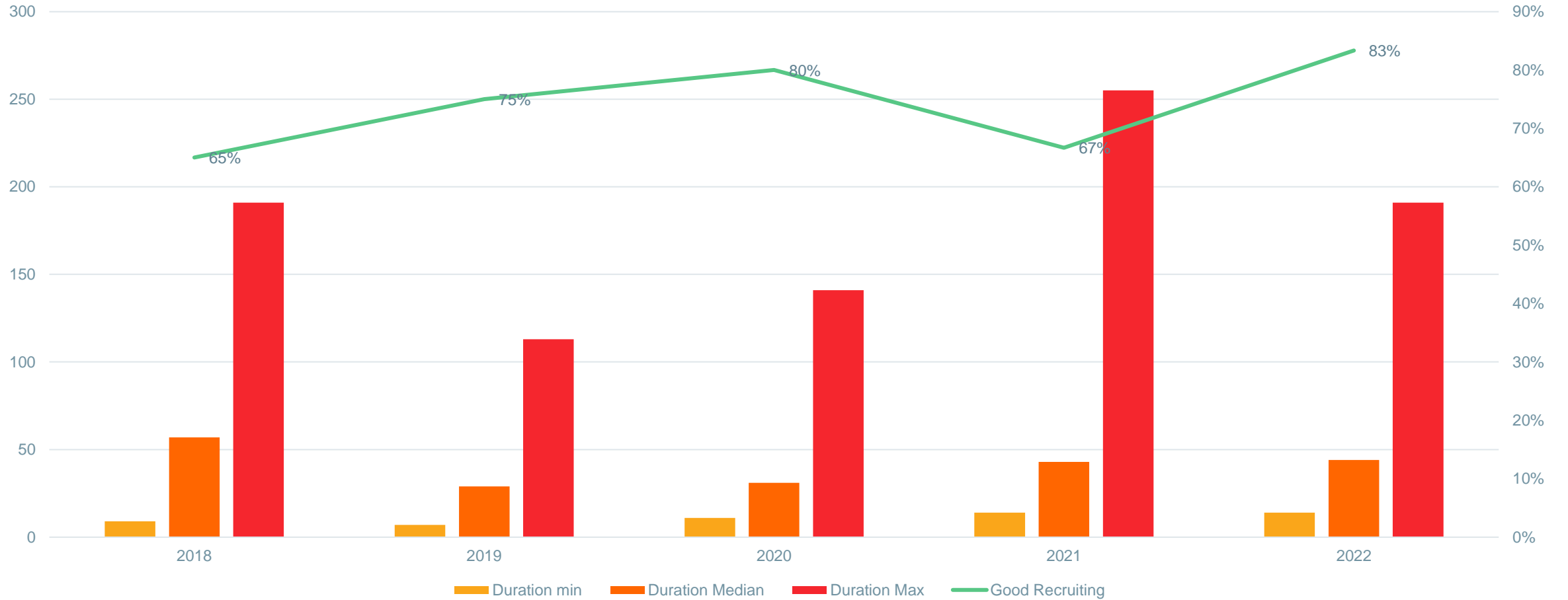
Difficult recruitment trials in comparison to all trials

	Average	Difficult recruitment
Fee min	1079	1900
Fee mean	2608	3046
Fee median	2623	2700
Fee max	5997	4950
Duration min	11	35
Duration mean	42	103
Duration Median	40	91
Duration Max	171	191
Inhouse Min	1	2
Inhouse Mean	5	4
Inhouse Median	6	4
Inhouse Max	20	10



# Graphs from SGS trials

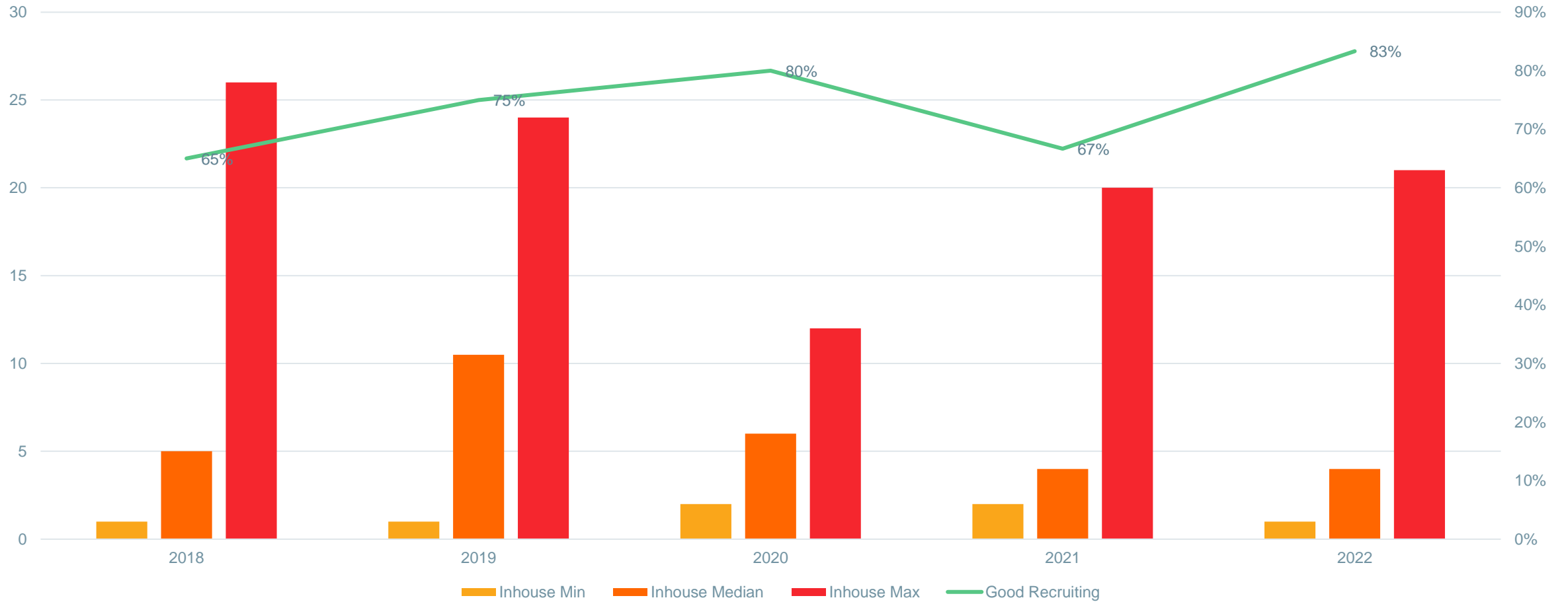
Trial Duration / recruitment





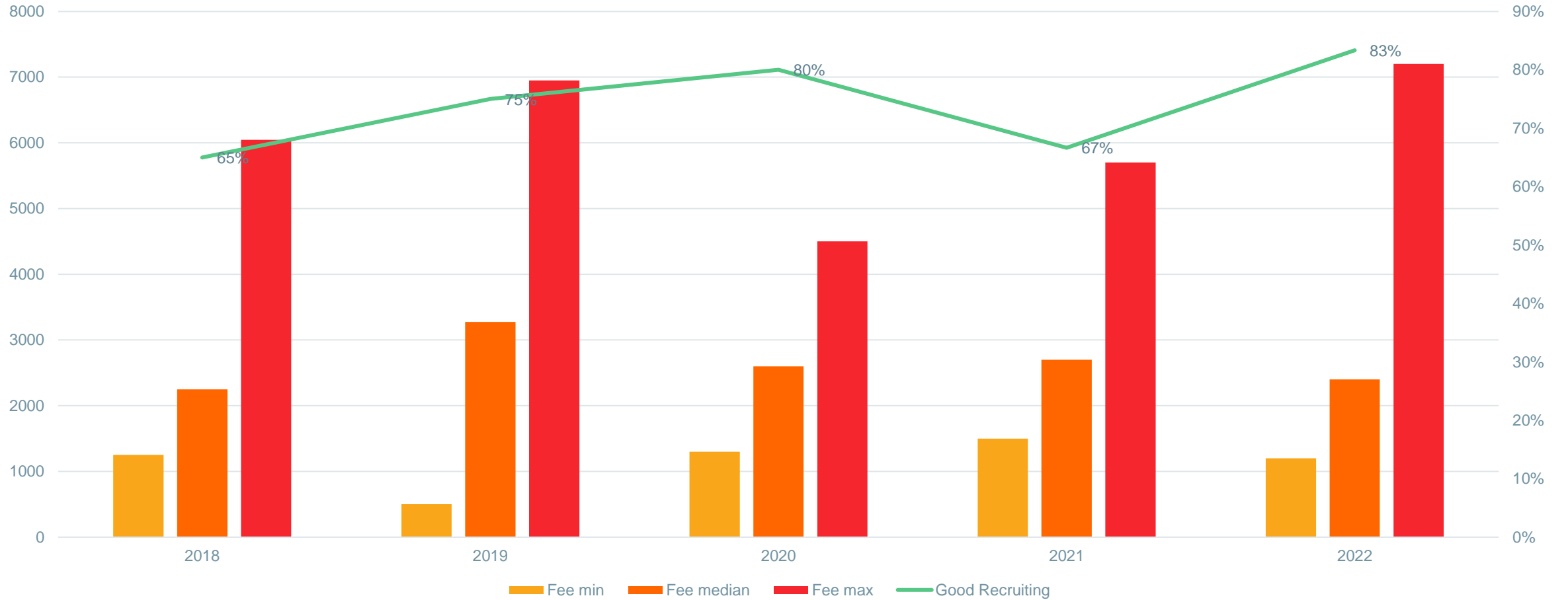
# Graphs from SGS trials

Amount of days inhouse / recruitment



# Graphs from SGS trials

Fee / recruitment



# Difficult recruiting trials

## Characteristics

- Long follow up
- Short inhouse stay
- Large molecule > small molecule
- Male 18-55 years
- Large trials



# What will the future bring?



# References

- 1: Gaudino M, e.a. Effects of the COVID-19 Pandemic on Active Non-COVID Clinical Trials. *JACC* 2021;76(13), 1605-6
- 2: Vissers M, e.a. The impact of the global COVID-19 pandemic on the conduct of clinical trials: Return to normalcy by considering the practical impact of a structured ethical analysis, *Br J Clin Pharmacol.* 2021;87(3) 837-44
- 3: Riccaboni M. e.a. The impact of COVID-19 pandemic on scientific research in the life sciences, *PLoS ONE*, 2022 17(2)e0263001
- 4: <https://databankklinischeproeven.be/> - Accessed 08MAY2023
- 5: <https://clinicaltrials.gov/ct2/search/advanced> - Accessed 08MAY2023
- 6: <https://drks.de/search/en> - Accessed 08MAY2023
- 7: <https://www.isrctn.com/editAdvancedSearch> – Accessed 08MAY2023
- 8: Deloitte, Ten Years on Measuring the Return From Pharmaceutical Innovation 2019, <https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/life-sciences-health-care/deloitte-uk-ten-years-on-measuring-return-on-pharma-innovation-report-2019.pdf>

