

BioCentury/BIO Survey (completed March 19, 2020)

- Majority of survey respondents were from US companies (87%),
- Majority of survey respondents were small companies with no FDA approved products: 71%
 - Companies with 1-5 products on market: 16%
 - Companies with >5 products on market: 13% (large companies)

Companies with plans to initiate a clinical trial

- in US/Canada: 92%
- in Europe: 64%
- in Asia Ex-China: 36%
- in China: 21%
- in LATAM: 17%
- in Africa & Middle East: 9%

Companies with **ACTIVE** clinical trials

- in US/Canada: 98%
- in Europe: 58%
- in Asia Ex-China: 41%
- in LATAM: 25%
- in China: 19%
- in Africa & Middle East: 15%

“very concerned” with initiating clinical trial

- in Europe: 65%
- in China: 57%
- in US/Canada: 47%
- in Asia Ex-China: 45%
- in LATAM: 30%
- in Africa & Middle East: 1%

“very concerned” with **ACTIVE** clinical trial

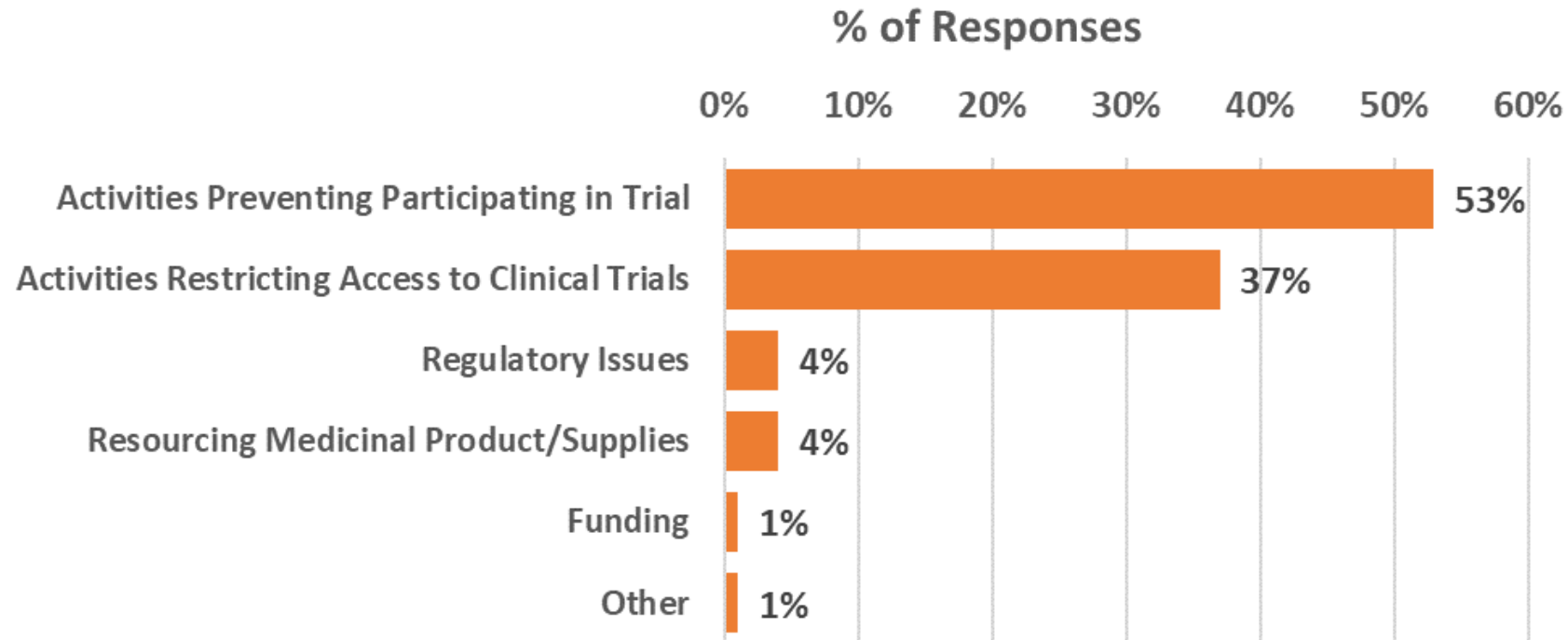
- in US/Canada: 49%
- in Europe: 48%
- in Asia Ex-China: 29%
- in LATAM: 16%
- in China: 10%
- in Africa & Middle East: 10%

Takeaways:

- Europe is of highest concern for those initiating trials
- US and Europe of highest concern for active trials

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Has your ability to conduct clinical trials been impacted by the coronavirus outbreak? (81% answered “yes”)



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Takeaways:

- High concern surrounding trial disruption and access
- Europe and US trials of highest concern
- Not as concerned about API/Supplies

Initiating ("very concerned")	Africa & Middle East	Asia ex-China (including Australia)	China	Europe (Western and Eastern)	Latin America	US & Canada
Supply of API	15%	25%	44%	29%	24%	22%
Other Supplies	20%	22%	39%	28%	27%	23%
Inability to enroll participants	43%	60%	54%	73%	33%	61%
Disruption of continuity of participation	37%	57%	51%	75%	45%	68%
Ability to test for COVID-19	35%	33%	39%	36%	24%	36%
Access to clinical trial sites	51%	60%	54%	70%	45%	63%
Health of clinical trial workforce	37%	46%	54%	58%	39%	47%
Active trials ("very concerned")	Africa & Middle East	Asia ex-China (including Australia)	China	Europe (Western and Eastern)	Latin America	US & Canada
Supply of API	20%	14%	30%	27%	28%	17%
Other Supplies	32%	24%	23%	33%	38%	24%
Inability to enroll participants	40%	57%	35%	65%	46%	61%
Disruption of continuity of participation	50%	58%	35%	71%	54%	71%
Ability to test for COVID-19	30%	29%	23%	34%	31%	35%
Access to clinical trial sites	50%	53%	35%	75%	58%	69%
Health of clinical trial workforce	37%	42%	27%	60%	52%	54%

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Rank level of concern the current or near-term impact of disrupted active or planned clinical trials due to coronavirus outbreak:
(1 “no concern” to 5 “very concerned”)

	1	2	3	4	5
Loss of investment dollars	2%	9%	17%	28%	44%
Negative impact on planned statistical goals submitted to agencies	7%	13%	19%	23%	38%
Loss of clinical trial data due to loss of clinical trial participants	2%	11%	14%	18%	55%
Loss of clinical trial data due to lack of continuity of participation	2%	10%	11%	26%	50%
Delay in active clinical development programs	0%	3%	14%	18%	65%
Inability to initiate clinical development program	3%	2%	18%	23%	53%
Other (Please specify below)	0%	0%	9%	18%	73%

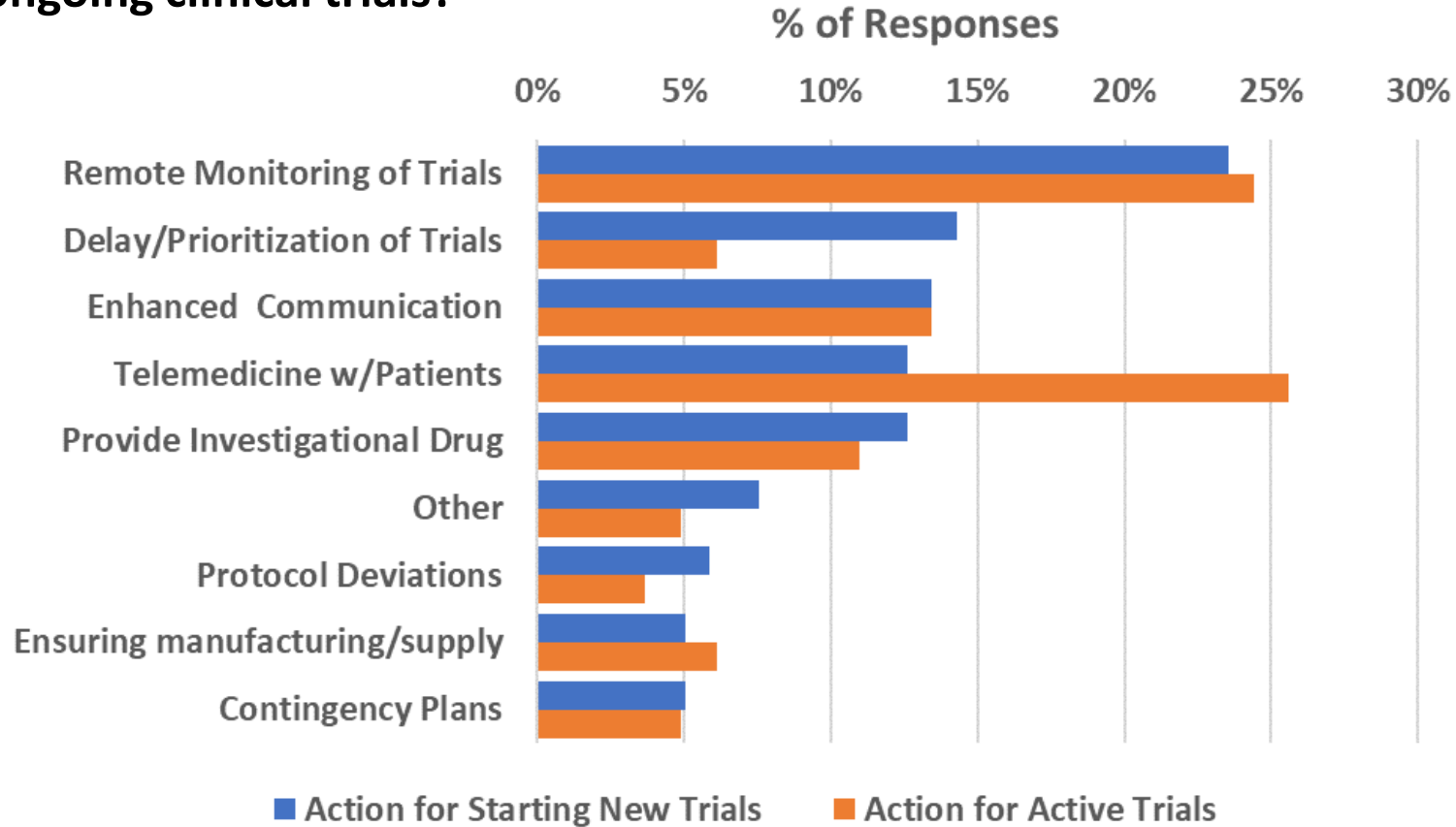
Other concerns: loss of continuity of how global clinical trials are run (each country/site with own government task force and recommendations)

Takeaways:

- All ranked “very concerned”
- Highest of concern were trial delays and disruptions of global multi site trials

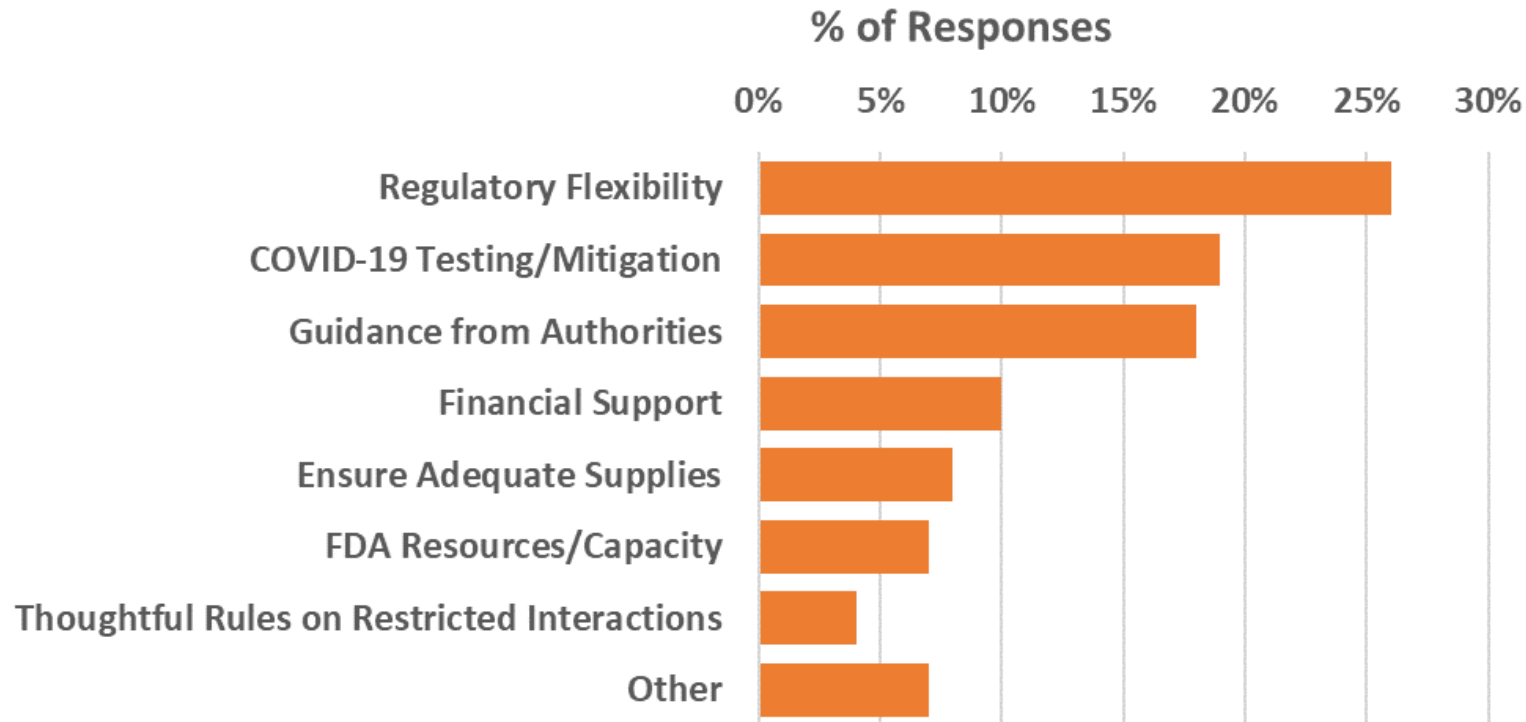
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What steps has your company taken to avoid disruption of upcoming/ongoing clinical trials?



BioCentury/BIO Survey (completed March 19, 2020)

What are the most important policies or government actions needed to mitigate against the impact of widespread disruption of clinical trials due to the coronavirus outbreak?



Regional Analysis of the Industry Pipeline Based on Citeline Database

Parameters and Limitations of Screening Citeline Database

- Trials from this dataset are “Active” drug intervention trials (in Phase I, I/II, II, II/III, or III) sponsored by a company.
- Trial tagged as “intended for US FDA pathway” are based on Informa PharmaProjects analyst assessment based on SEC filings, FDA filings, investor reports, company press releases, and company location.
- Trials reported herein are not “programs”. A drug program could theoretically have many trials.
- Data captures any enrolled patients from a specific region. Thus, whether 1% or 99% of the enrolled trial participants, a trial will be counted as having some patients from that region.
- Trials with multiple sites in multiple regions will be counted more than once. For example, if half of enrolled patients are from China and the other half USA, the trial will be tallied in both the China count as well as the USA count. Thus, the % per region will not sum to 100%.
- For criteria such as “% Biologic”, the denominator is the # that have been tagged. Some Phase I trials have “undisclosed” modality.

Regional Analysis of the Industry Pipeline Based on Citeline Database

Takeaways:

Trial level data:

- 57% of trials intended for FDA pathway enroll ex-US patients
 - Most ex-US trials centered in Europe (33% of global trials) with Asian patients enrolled in >14% of trials and 13% of global trials enroll patients from China
- Gene therapy trial arms more concentrated in China as a % of regions trials
- Vaccines trial arms concentrated in Asia and Africa as a % of regions trials
- Fewer rare disease trial arms (as a % in region) in Asia vs. rest of world
- Trials w/pts in developing countries ex-Asia (LATAM, Africa, Canada, East Europe) are more concentrated in Phase III
- Trials for US/Europe patients have highest enrollment at Phase II (near 50%)

Drug level data:

- Matches with trial-level data albeit at higher % as individual drugs can be in multiple trials

Company-Sponsored ACTIVE Drug Intervention Trials* (Phase I, II, III) Worldwide n=13,490

Phase I-III drug trials (all drug trials)	Africa	LATAM	China	Asia Ex-China	E. Europe	Europe	Canada	USA	Global
# drug trials w/patients in regions	401	922	2,205	2,152	1,786	4,436	1,703	6,519	13,490
% global drug trials w/patients in regions	3%	7%	16%	16%	13%	33%	13%	48%	100%
% of regional trials by modality									
# Biologic in region	182	434	1,057	972	746	1,919	774	2,917	5,907
% Biologic in region	47%	47%	47%	44%	43%	44%	46%	44%	44%
% Biologic in of worldwide biologic trials	3%	7%	18%	16%	13%	32%	13%	49%	100%
# Gene Therapy	5	9	171	45	12	136	49	338	650
# Vaccine	35	34	65	96	43	131	33	205	569
% Gene Therapy of 5,907 trials	1%	1%	8%	5%	1%	3%	3%	5%	11%
% Vaccines of 5,907 trials	9%	4%	3%	10%	2%	3%	2%	3%	10%
% of regional trials for Rare Disease									
# Orphan trials in region	201	505	714	1,099	970	2,476	1,055	3,685	6,428
% Orphan in region	49%	53%	31%	49%	53%	54%	59%	54%	48%
% of all Orphan trials worldwide	3%	8%	11%	17%	15%	39%	16%	57%	100%
Phase I-III drug trials (FDA pathway)									
# drug trials for FDA pathway	260	575	1,084	1,246	1,194	2,823	1,208	4,953	8,621
% drug trials for FDA pathway (of 13,490 ww)	3%	7%	13%	14%	14%	33%	14%	57%	100%
% of regional trials by phase									
Regional % in Phase I	1%	2%	35%	21%	6%	17%	11%	24%	28%
Regional % in Phase II	21%	24%	32%	42%	33%	47%	38%	50%	48%
Regional % in Phase III	78%	73%	33%	37%	61%	36%	51%	26%	25%

Drugs in Trials

(Phase I, II, III) Worldwide n=4,933

Drugs in Phase I, II, III trials	Africa	LATAM	China	Asia Ex-China	Canada	E. Europe	Europe	USA	Global
# drugs (w/trials in regions)	247	485	1,018	1,191	919	949	1,988	2,787	4,933
% drugs (w/trials in regions)	5%	10%	21%	24%	19%	19%	40%	56%	100%
Drugs by modality (w/trials in region)									
Biologic	104	186	451	459	340	346	760	1,110	2,024
% Biologic in region	42%	38%	44%	39%	37%	36%	38%	40%	100%
% Biologic of global 4,933 drugs	2%	4%	9%	9%	7%	7%	15%	23%	41%
Gene Therapy	4	7	94	26	28	8	78	190	310
Vaccine	26	24	45	76	24	38	98	138	322
% Gene Therapy of biologics (in region)	2%	1%	9%	2%	3%	1%	4%	7%	15%
% Vaccine of biologics (in region)	11%	5%	4%	6%	3%	4%	5%	5%	16%
% Gene Therapy of global 4,933 drugs	0.1%	0.1%	1.9%	0.5%	0.6%	0.2%	1.6%	3.9%	6%
% Vaccine of global 4,933 drugs	0.5%	0.5%	0.9%	1.5%	0.5%	0.8%	2.0%	2.8%	7%
Drugs for Rare Disease (w/trials in region)									
Orphan	104	219	211	405	430	412	750	953	1,203
% Orphan in region	49%	53%	31%	49%	59%	53%	54%	54%	100%
% Orphan of global 4,933 drugs	2%	4%	4%	8%	9%	8%	15%	19%	24%
Drugs in Phase I, II, III trials for FDA pathway									
# drugs (w/trials in region for FDA pathway)	239	470	530	860	876	827	1,568	2,666	3,433
% global drugs intended for FDA pathway	7%	14%	15%	25%	26%	24%	46%	78%	70%