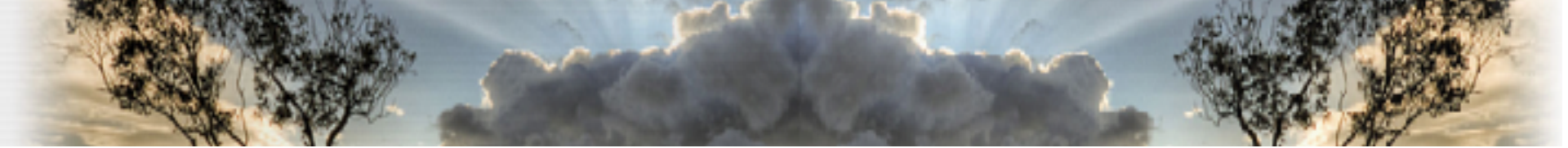


EBF Open Symposium

N° 13 From Cyberspace - Staying Connected

17-20 November 2020

To Ship or not to Ship

Finger-on-the-pulse (FotP)

Matt Barfield, on behalf of the EBF >>

Finger-on-the-pulse (FotP)

- FotP gives an excellent opportunity to quickly get input across the EBF community on a particular question or subject
- Topics are varied and are typically related to regulations, technology or current issues facing Bioanalysis
- Output gives in-site into other companies experiences and often solutions and ideas

Content of this FotP – To ship or not to Ship

With the introduction of The Human Genetic Resources Administration of China (HGRAC) regulations in July 2019 there is a sense that exporting samples from China is now more complex. This survey was designed to draw on the experiences of the community.

Twelve questions were submitted to investigate:

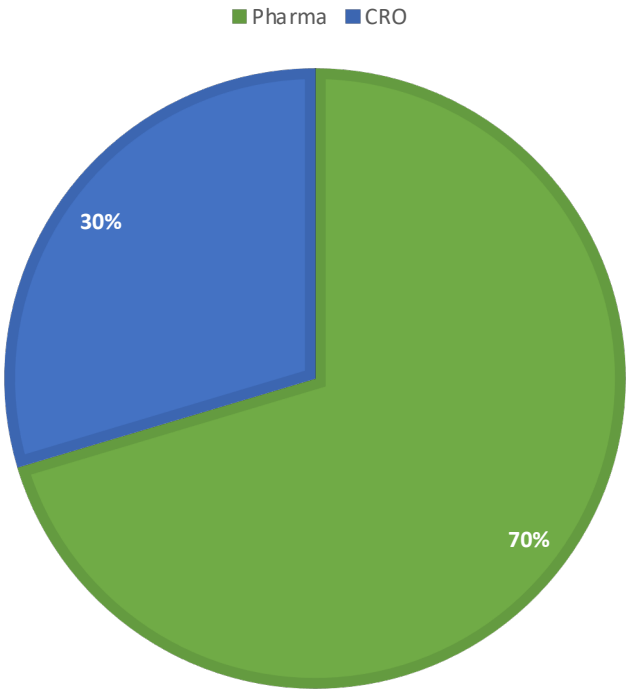
- Are companies analysing china samples (PK, Biomarker, ADA..) locally or exporting
- Do companies see exporting China samples as a risk
- Dealing with Intellectual Property when supporting studies with exploratory endpoints in China

➢ 27 responses were received

FotP Questions

1. My organisation is (Pharma/CRO)?
2. Do you support bioanalytical clinical analysis from China e.g. PK, Biomarker, ADA.....?
3. Is your goal to: Support analysis in China or export the samples from China for analysis?
4. If you are exporting, are you successful?
5. What areas are you successful in? Early stage (Phase 1 - 2), Late stage (Phase 3) or both?
6. What areas are you not successful in? Early stage (Phase 1 - 2), Late stage (Phase 3) or both?
7. Do you see exporting samples from China as a risk?
8. Have samples not been analysed due to issues with export from China?
9. Do you conduct studies in China with an exploratory endpoint e.g. BioMarkers?
10. If yes to question 9, do you export?
11. If no to question 10 do you share the IP with the PI?
12. Do you find it a challenge to ship into China e.g. reagents, control matrix …?

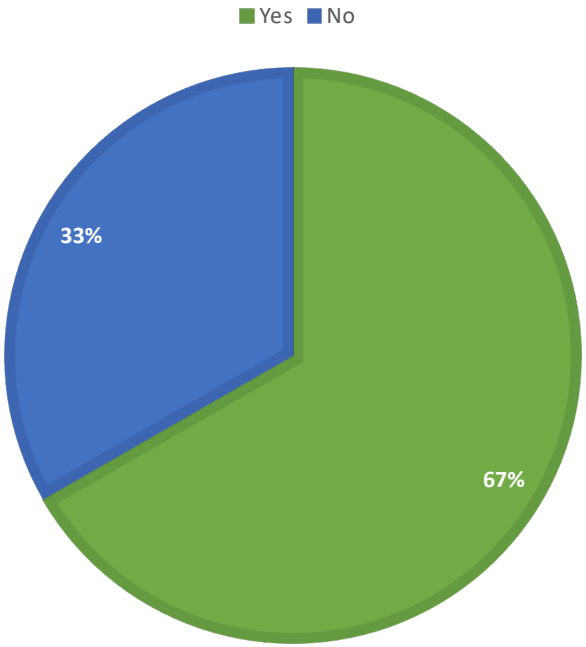
1. My organization is



Pharma	19
CRO	8

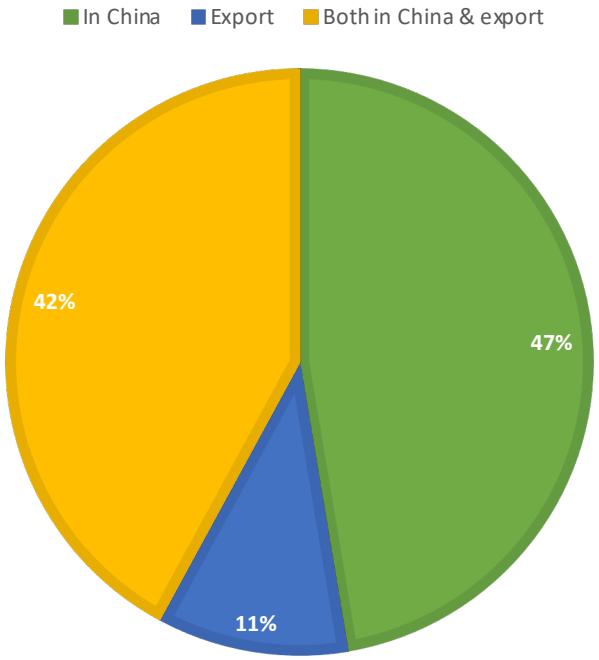
EBF

2. Do you support bioanalytical clinical analysis from China e.g. PK, Biomarker, ADA.....?



YES	18
NO	9

3. Is your goal to: Support analysis in China or export the samples from China for analysis?



In China 9
Export 2
In China & export 8

Comments

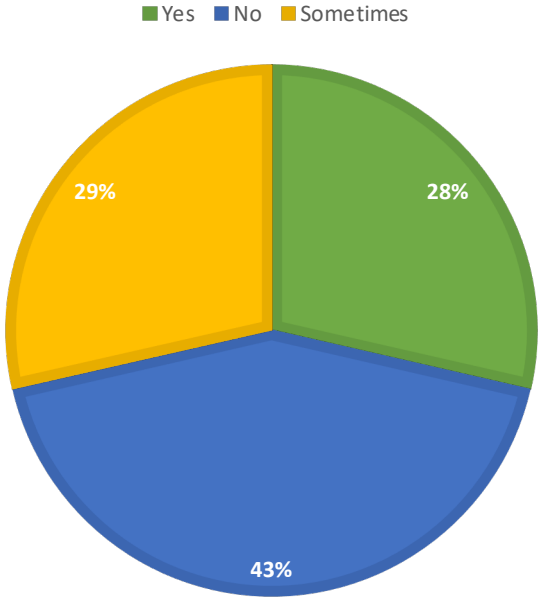
We try to export samples but now it is difficult without a strong scientific rationale (such as ICP/MS, for example)

Regarded as too complicated/ not feasible to export

For China only study support BioA in China by 1st intent.

If global study with China leg, then export if possible (although project teams push back on exporting samples… too much effort & risk)

4. If you are exporting, are you successful?



Comments

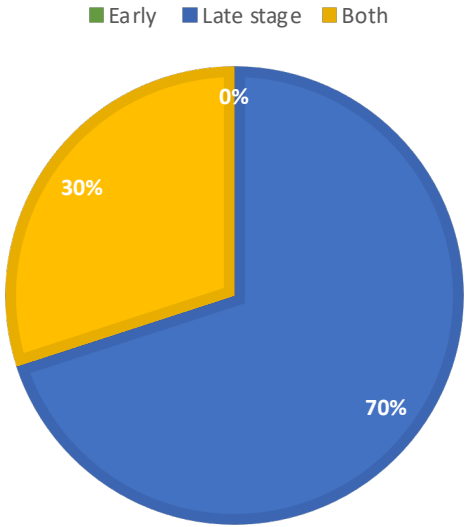
Only possible when time of analysis is flexible

Rarely (one recent application was rejected)

It gets more difficult over the last year, following a change in Chinese regulations

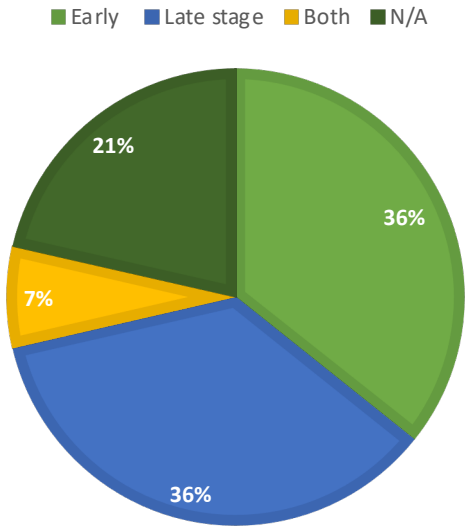
YES	4
NO	6
Sometimes	4

5. What areas are you successful in? Early stage (Phase 1 - 2), Late stage (Phase 3) or both?



Early	0
Late stage	7
Both	3

6. What areas are you not successful in? Early stage (Phase 1 - 2), Late stage (Phase 3) or both?



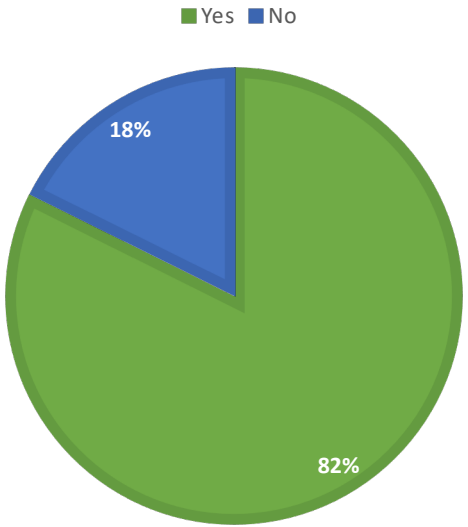
Comments

Depends e.g. on the leading site, submission before/after new regulation release

Export has been getting more and more difficult since last July

Early	5
Late	5
Both	1
N/A	3

7. Do you see exporting samples from China as a risk?



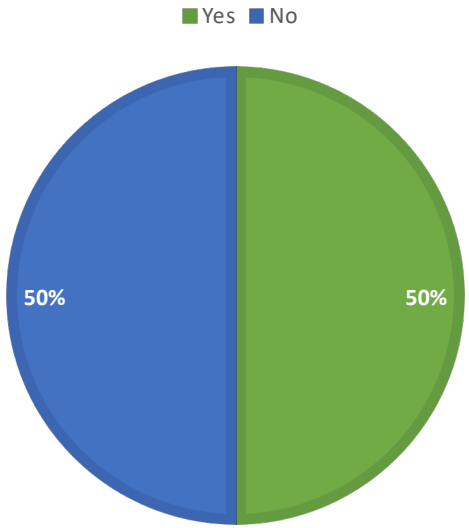
YES	14
NO	3

Comments

Biomarker: Now sample exportation is avoided as much as possible in all trial studies in China

High risk of not obtaining approval and subsequent HGRAC delays

8. Have samples not been analysed due to issues with export from China?



YES	7
NO	7

Comments

We haven't had samples not analysed, but there are occasions when a team will choose to exclude certain analytes from the China arm due to concerns about the complexity of exporting /setting up the assays in China

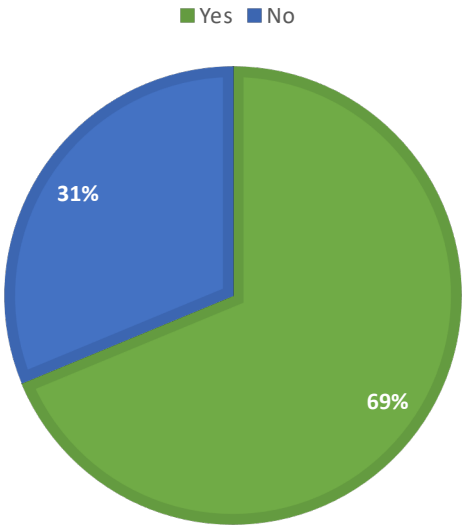
Biomarker: Some samples collected in China are pending for analysis since last summer

PK/ADA: Delays in sample analysis for some studies. Potential samples that will not be analysed in time for submission in an ongoing study.

Samples out of stability due to delays

Had to change strategy and analyse in another lab in China

9. Do you conduct studies in China with an exploratory endpoint e.g. BioMarkers?

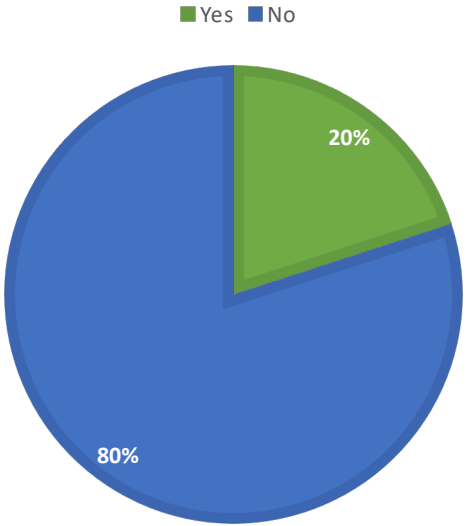


Comments

Only if the assays are already available in China

YES	11
NO	5

10. If you do conduct studies in China with an exploratory endpoint do you export?

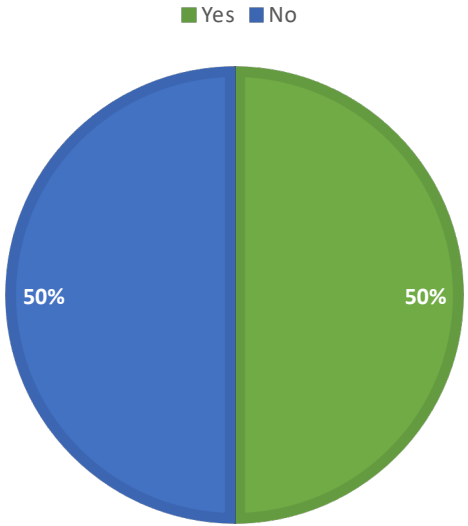


Comments

For most studies we do not get permission to export these samples

Yes but depends on timeline for analysis and complexity of method

11. If no to question 10 do you share the IP with the PI?



Comments

Depends on the assay

Project teams either reject site or negotiate extent of IP sharing

YES	1
NO	1

12. Do you find it a challenge to ship into china e.g. reagents, control matrix …?

Comments

Heard that you need 3 month to have authorisation to export critical reagents to China

For RIA the labelled compound is very difficult. But also spiked QC's have been troublesome = >2 months to get into China

Would tend to send samples to US/EU CRO site for them to ship to their China site

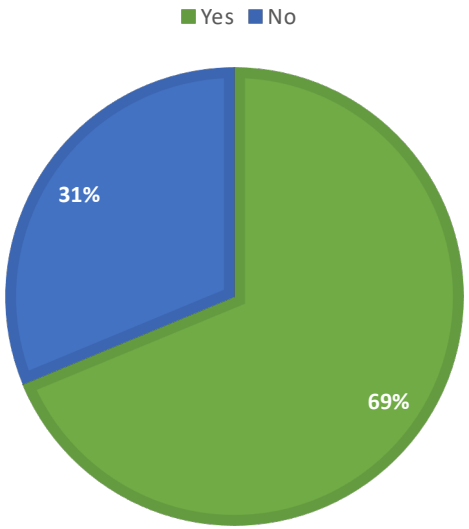
Not now that we understand the process. Only downside is degree of planning necessary and time required

After COVID-19 outbreak restriction on reagent import increases cost to the current assays or causes more hurdles for setting up new assays in China

A recent import permit for study samples was not approved due to lack of Covid-19 exclusion criteria in the study (which was initiated pre-Covid)

A previous shipment was approved, but was delayed significantly in customs

Similar to the US



YES	11
NO	5

Summary and conclusions

- Supporting studies originating from China is not straightforward
- Exporting samples since the implementation of HGRAC has become far more complex. For the majority analysis is conducted in China
- There is a real risk now in exporting the samples with examples of elongated timelines with important deadlines being missed and samples not analysed. Generally only late stage is considered for export but this also carries a risk
- Exploratory Biomarkers are even more complex with sharing of intellectual property, these are generally analysed locally with recent examples of export not being allowed
- Shipping into China also shows difficulties but companies are finding more efficient routes and ways to simplify the process

Acknowledgements

To all of the EBF community that contributed to the FotP

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