JAMES LIND INSTITUTE

PATIENT INSIGHTS:
The need for patient feedback

Delivering feedback on clinical trial results and meeting the needs of participants

JAMES LIND INSTITUTE

APRIL 2020 REPORT

1.280 answers from community members in three European countries

Our findings are based on 1.280 answers from our community members in United Kingdom, Sweden, and Denmark.

Uncovering the needs and preferences of participants in relation to feedback on clinical trial results. New data reveals the unfortunate gap between existing conduct among professionals and constructive patient centric approach.
This report provides useful recommendations for an improved practice.

Trial participants want feedback

98% of all clinical trial volunteers would like some form of feedback after participation. Did the study succeed in finding a new treatment? Was their time worth the effort?

Unfortunately, 60 — 90% of trial participants never receive any feedback from their trial. Although the Declaration of Helsinki clearly states that patients should have the option to receive results of the study, the vast majority of clinical trial volunteers never do.
Non-reporting from trial sponsors is a problem that needs to be addressed*. James Lind Institute wants to do our part in solving this issue. Because participants want feedback and we see that trial sponsors actually want to deliver trial results to enrollees, but don't know how. This report outlines important steps to be taken.
This report focuses on the five essential aspects of clinical trial feedback:

1. DEMAND: How many patients want feedback?
2. RECIPIENTS: What kind of patients demand clinical trial feedback?
3. COMMUNICATION: What do trial participants expect to be informed about?
4. MEDIA: How do trial participants prefer to receive feedback?
5. LANGUAGE: In what language should the feedback be provided?

*TranspariMED estimates that across Europe, 36% of all drug trials are missing results in the EudraCT trial registry. In the US it's estimated 2,400 trials are breaching the rules of trial results reporting.

Primary findings

1. DEMAND:
   How many patients want feedback?
   98% of all clinical trial volunteers want to receive feedback.

2. RECIPIENTS:
   What kind of patients demand clinical trial feedback?
   All potential participants who attend first visit and sign an informed consent form, not just the randomized participants.

3. COMMUNICATION:
   What do participants expect to be informed about?
   The overall results of the trial – not minor details.

4. MEDIA:
   How do trial volunteers prefer to receive trial feedback?
   The majority prefer to have it sent to them by email.

5. LANGUAGE:
   In what language should the feedback be provided?
   Patients prefer their native language.

Demand

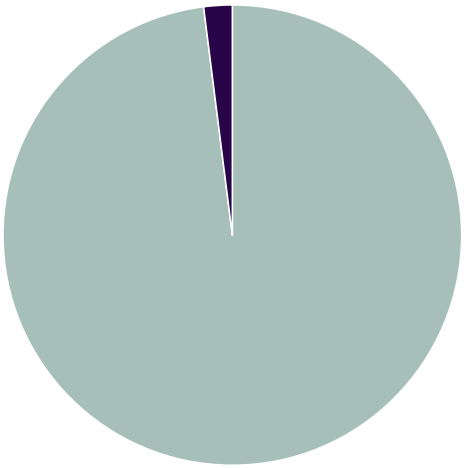
At James Lind Institute we consider it to be a fundamental right for patients to be informed of results when having been in a clinical trial. Patients deserve feedback.

Our research shows that altruism is as strong a factor in patient commitment as personal motives in clinical studies. Volunteers are driven by a profound enthusiasm for research and want to help develop better treatments for new patients. This commitment becomes evident in the shared desire for feedback on results among clinical trial participants.

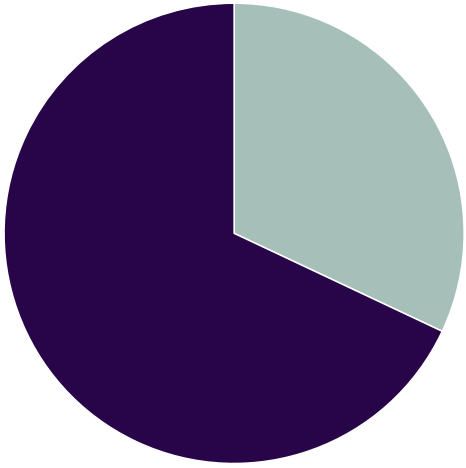
But 68% of participants in clinical trials get no feedback at all.

The World Medical Association Declaration of Helsinki states that all volunteer patients should have the option to receive information on study results. According to TranspariMED, 36% of all European trials fail to list results on the EudraCT trial registry.

2,400 US trials are estimated to breach the reporting rules of trial results.



Want feedback	98%
Do not want feedback	2%



Received feedback on trials	32%
Participated without getting any feedback	68%

Recipients

98% of all trial volunteers want feedback, but must they all receive it? The patient centric answer is: All volunteers considering themselves to be participants should.

Some volunteers are randomized into trial, others screened out. Often, the latter never hear from research staff again despite visits and screening tests. We have pre-screened thousands of patients and know that they consider themselves to be participants when signing the consent form at first visit. They want and deserve to get feedback. According to Beth Harper, President at Clinical Performance Partners, approx. 32% of all volunteers fail screening criteria*. Most never know trial results. That's not good enough: Trusting patients give out their time, earning our respect and should get feedback in return.

> Quote from Pharma (patient engagement staff)
> Sponsors want to inform all participants, but we are legally prevented from obtaining contact details. It's difficult to ensure they get the results at the end of the trial.

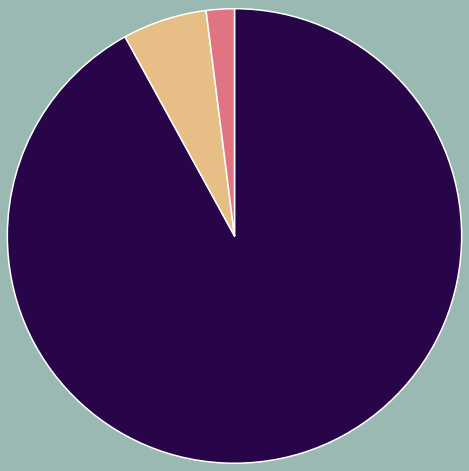
James Lind Institute suggests include both those signing the informed consent form and randomized volunteers in the group considered 'clinical trial participants'.

*forteresearch.com/news/strategic-patient-screening-qa-feasibility-budgets/

Communicating trial results in a patient centric way

What information do participants expect?
92% prefer a brief report informing participants of trial results. Only 6% want the full scientific report.

Sponsors need to adapt new initiatives to be able to inform and educate participating patients about their clinical studies.



Lay summary	92%
Full scientific report	6%
No feedback wanted	2%

Trial participants are interested in the overall results – not scientific minutiae. So the lay summary must answer essential questions and be to the point.

9 questions to answer in a lay summary:

- What was this study about?
- Why was the study needed?
- Which medicines were studied?
- Who participated in the study?
- How was this study done?
- What were the results of this study?
- Were there any unwanted effects?
- Are there additional studies?
- Where can I find more information?

Pharmaceutical company Boehringer Ingelheim works with regulators to develop summaries of trial results to participants*.

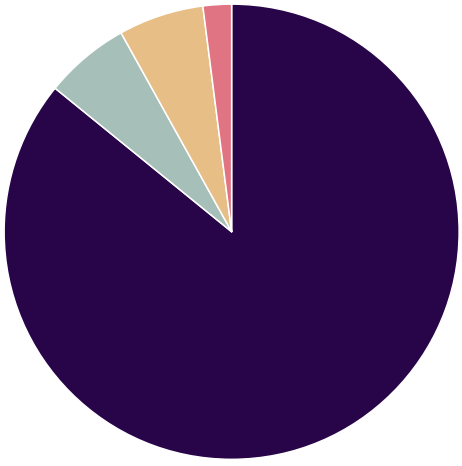
They provide an easy-to-use, informative digital overview of their trials with available lay summaries, many even in multiple languages.

trials.boehringer-ingelheim.com/trial_results/clinical_trials_overview/clinical_trial_result.c=n.i=.html?document_type=2

Media

Sponsors must register results of completed trials in the EU Clinical Trials Register or at ClinicalTrials.gov within 12 months*.
But few patients ever visit these registers, and they don't know when or where specific trial results are posted. Most patients never see results or receive feedback from their clinical trial. This is frustrating for patients, and must be improved drastically.

Many sponsors provide the lay summaries that trial participants want. But do they actually reach participants? Patients are encouraged to see if new material is made available. It's not unusual for a year to pass from end of study to the appearance of the lay summary, so there's a risk that many participants will never see it. According to our new research on the subject, the vast majority of trial participants prefer trial feedback to be sent to them personally by email.



How would you like to receive your trial feedback?

By email	85%
Printed version	6%
Both by email and in print	6%
I do not want any feedback	2%

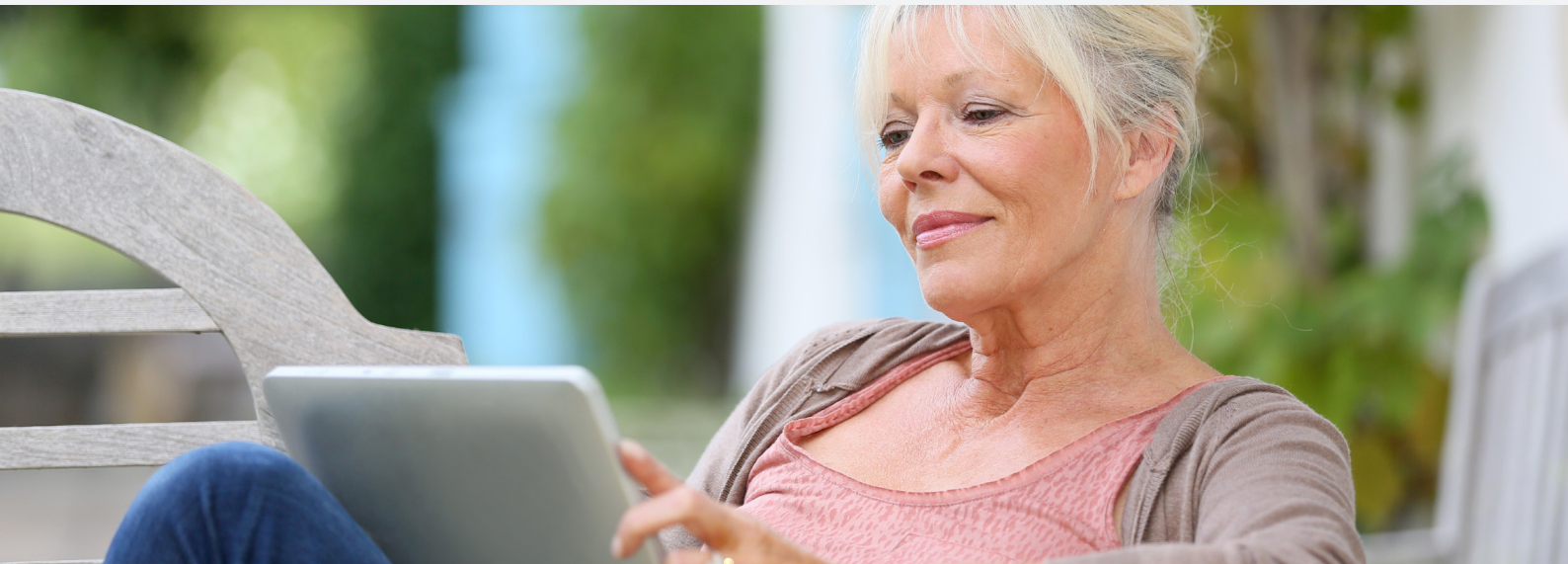
*Standards defined by FDA's Amendment Act of 2007 and the EU's clinical trial regulation.

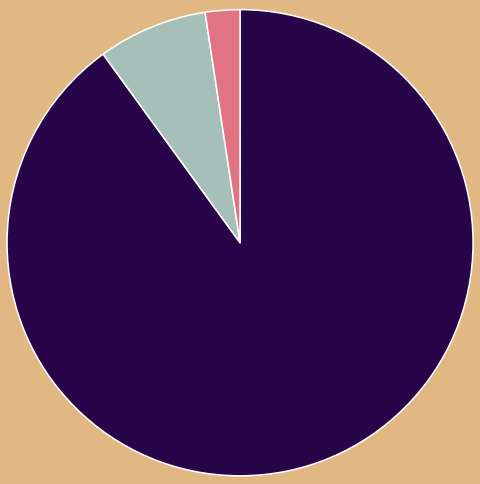
Language

Scientific reports uploaded to EU Clinical Trials Register and ClinicalTrials.gov are all in English. Their terminology and sheer length makes for a difficult read even to patients with English as their first language and useless to many non-English speaking participants.

Although some sponsors provide shorter lay summaries of trial results in easy-to-understand phrasing, the vast majority of summaries are available only in English.

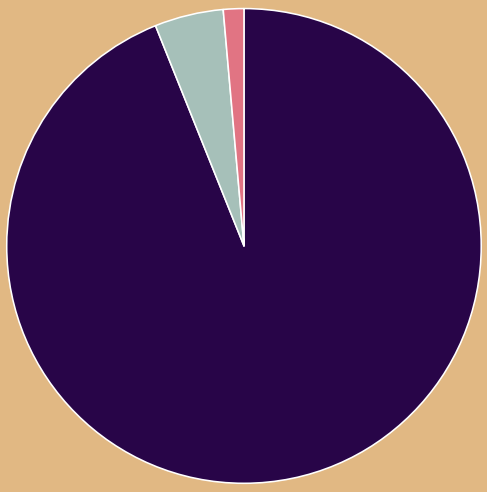
Our data shows clearly that trial participants want more. In non-English speaking countries, nine out of ten volunteers request trial feedback in their own language. These results are remarkable, since both Swedes and Danes are quite proficient in English. Safe to assume that the demand for local lay summaries must be even greater in European countries with patients with a presumably lesser understanding of the English language.





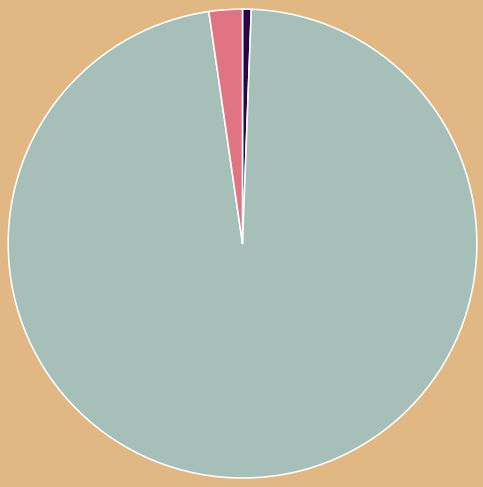
Preferred language in Sweden:

My native language	90%
English	7,6%
Do not want feedback	2,4%



Preferred language in Denmark:

My native language	94,2%
English	4,7%
Do not want feedback	1,4%



Preferred language in United Kingdom:

My native language	0,6%
English	97,2%
Do not want feedback	2,3%

Lay summaries are brief, usually five pages, shorter than initial patient information.
Requiring a manageable effort and fewer resources, lay summaries can easily provide trial participants with results in their native tongue.

In conclusion

James Lind Institute — the international patient organization focusing on participants in clinical trials – has carried out a research project to seek out patient preferences regarding clinical trial feedback.
The results presented in this report are convincing and clear.

Primary findings:

- 98% of all clinical trial volunteers want to receive feedback.
- Participants are not just the randomized enrollees. Volunteers consider themselves to be participants from first visit and signing the informed consent form.
- Participants expect to be informed of the overall results, not the scientific details.
- Participants prefer to receive trial feedback by email first and foremost.
- The feedback should be provided to trial volunteers in their native language.

James Lind Institute wants to help solve this problematic issue, because patients want adequate feedback and trial sponsors actually want to provide results to patients — but neither can solve it alone.

For further data analysis,
please contact Rasmus Hjorth
(+45) 3141 4082
rasmus@jameslindinstitute.org

About James Lind Institute

James Lind Institute is an international patient organization founded in 2011. It facilitates research focused patient communities in Europe, guiding patients in their clinical trial engagements.

Due to our many members and unique international character, James Lind Institute can take action on the issues confronting patient centricity in clinical trials, such as understandable communication, gentle protocol design, attentive enrollment, adequate feedback on research results, and more.

James Lind Institute
Købmagergade 60
1150 København K
Danmark

jameslindinstitute.org

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