Your Feedback on Study Result Summaries

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Alliance Fall 2016 Meeting

Have you heard of Alliance Study Result Summaries (SRS)?

1. Brief background
2. Example (CALGB 40603)
3. Publications and Health Outcomes Committees want your feedback!
   - Fun with electronic “clickers”
   - Paper, if we must

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ALLIANCE STUDY RESULT SUMMARIES

The **Alliance for Clinical Trials in Oncology** provides summaries of results of its studies in an easy-to-read format. These summaries highlight recently published Alliance study results and resources for more information. To find study results summaries, click on type of cancer or condition below.

Thank you to everyone who has participated in these clinical trials. Your contributions will help new patients who are diagnosed with cancer.

Type of cancer

- Breast Cancer
- Brain-related Cancers (including **glioblastoma**)
- Gastrointestinal - GI (including **colon**, **esophageal** and **pancreatic** cancers)
- Genitourinary - GU (including **bladder**, **kidney** and **prostate** cancers)
- Leukemia
- Lymphoma
- Melanoma
- Multiple Myeloma
- Respiratory (including **lung** and **mesothelioma** cancers)
- Transplant

Rare tumors

- Angiosarcoma (cancer of the **inner lining** of **blood vessels**)

Other conditions

- Other Treatment Studies
- Managing Side Effects and Symptoms of Treatment
- Improving How Care is Given
- Determining Health Outcomes

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Background: how these started

- 2005+ CALGB CARE: research on returning results
  - Ann Partridge et al (references for all at end of presentation)
- 2008/2009 research (Shalowitz/Miller, Sood)
  - 90% trial participants want results of their clinical trial
  - 89% don't understand trials until a result summary (Getz)
- 2014: EMA (FDA in Europe) created a regulation
  - All trial sponsors publish a public summary
- 2015: MRCT Center Return of Results Working Group
  - Guidance Document and Toolkit
- 2015: Transcelerate, PHRMA, and EFPIA recs
  - Guidance Document and Toolkit
- 2016:
  - HHS regulations & NIH policy on results in clinicaltrials.gov
  - NCI CTEP supports study result summaries
  - Health Literacy Media (HLM) Plain Language Research Summaries

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Current picture

- Alliance leads in NCTN
  - Over 40 summaries since 2009
    - trials > study result summaries
- Never promoted
  - Used? Useful?
- Publications & Health Outcomes Committees want your feedback!
  - Also plan survey with Alliance trial participants

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Alliance Public Study Result Summary

What the study is about

This cancer study asked if adding different kinds of cancer drugs to a common treatment given before surgery would shrink the breast tumor for women who had triple-negative breast cancer.

The full title of this study is: CALGB 40603 (Alliance) - Paclitaxel With or Without Carboplatin and/or Bevacizumab Followed by Doxorubicin and Cyclophosphamide in Treating Patients with Triple Negative Breast Cancer That Can Be Removed by Surgery

Why the study was done

15-20 of 100 women (15-20%) with breast cancer have "triple-negative breast cancer" (TNBC). This means the cancer cells do not use the hormones estrogen (ER-), progesterone (PR-), or a growth factor called HER2 (HER2-). TNBC is more common in younger women, African-Americans, Hispanics, and women who inherit a gene called BRCA1.

- Since it does not respond to agents that target the hormone receptors or HER2, the only available, proven effective treatment for TNBC is chemotherapy. In patients with TNBC that has not spread to other parts of their bodies (stage I-III), treatment with standard chemotherapy drugs, such as doxorubicin, cyclophosphamide and paclitaxel, significantly reduces the risk that the cancer will recur (come back), metastasize (spread to other parts of the body), and cause the death of the patient. However, even with these treatments, the prognosis for TNBC is worse than for other types of breast cancer.
- To develop new, more effective treatments for TNBC, it would help to know which patients are more likely to recur despite receiving the standard treatment. One way of telling which patients are more likely to do well or not is by assessing their response to standard chemotherapy given before surgery, called preoperative or neoadjuvant chemotherapy. While TNBC breast tumors shrink in most patients who receive this treatment, in about 35% of TNBC patients the cancer completely disappears, so that at surgery all that's left is scar tissue where the tumor used to be; this is referred to as a pathologic complete response (pCR).
- In TNBC patients who achieve a pCR, the risk of the cancer coming back is only 10-15% (from cancer cells that had spread elsewhere in the body before the patient started treatment and were not killed by the chemotherapy despite the disappearance of the cancer in the breast), while in patients who do not achieve a pCR the risk of cancer recurrence may be as high as 40-50%.
- In addition to allowing researchers to evaluate the effectiveness of the treatments, by shrinking the breast tumor neoadjuvant chemotherapy may allow a patient who would have required a mastectomy to undergo breast-conserving surgery (a lumpectomy or partial mastectomy) instead.
- In designing the clinical trial, we hypothesized that a higher pCR rate with the study treatments compared to the standard treatment might lead to fewer patients recurring and dying of their cancer. In addition, we would know the results more quickly (as soon as patients have their surgery) than waiting to see how many patients would recur after surgery.
- We decided to test adding the chemotherapy drug carboplatin, because TNBC appears to be especially sensitive to the way that this drug attacks cancer cells, and the anti-blood vessel forming agent bevacizumab, because there is evidence that TNBC relies on the formation of new blood vessels to grow and spread. We also believed, based on prior studies, that these drugs could be added to the standard chemotherapy regimen without causing a large increase in side effects.
- We also wanted to study a number of characteristics of each patient's cancer to see if we could identify any that would help to predict the likelihood of achieving a pCR, and whether adding carboplatin or bevacizumab would increase that likelihood; this is why we required that patients have research biopsies of their breast tumors before starting treatment.

New approach – health literate

Alliance for Clinical Trials in Oncology

NCI National Clinical Trials Network, a National Cancer Institute program

Tested more medicines with common treatment for triple-negative breast cancer

Study at a glance

NCT00861705

This study looked at adding 2 medicines

- Bevacizumab is also called Avastin. It was given in the vein.
- Carboplatin is also called Paraplatin. It was given in the vein.

Who should read this study

Results of this study apply only to people like those in the study. Results may not be the same for other people or for other kinds of breast cancer.

What was studied

Researchers studied what happened when bevacizumab and carboplatin were added to the common treatment before surgery.

Researchers wanted to see if the medicines:

- Were safe
- Helped make breast cancer tumors shrink

Who was in this study

443 patients with triple-negative breast cancer, which means their cancer did not depend on:

- Estrogen receptors
- Progesterone receptors
- HER2

Their cancers were called stage 2 or 3. They did not have any treatment before joining the study.

What were the main results of this study

- Bevacizumab is not likely to help this group of people
- Carboplatin is likely to help this group of people

The 2 study medicines made tumors go away before surgery in more patients than the common treatment.

Both medicines caused more side effects in patients, including some serious ones. Side effects were most serious in the groups that took bevacizumab.

Main results

Groups 2, 3 and 4 all had more patients whose breast tumors disappeared by the end of treatment before surgery. This is called pathologic complete response or pCR. Group 1 did not have as many patients with this result.

These results did not measure how long people lived or if their cancer returned. Prior studies show that patients with pCR might live longer and are less likely to have their cancer return. These findings need more study.

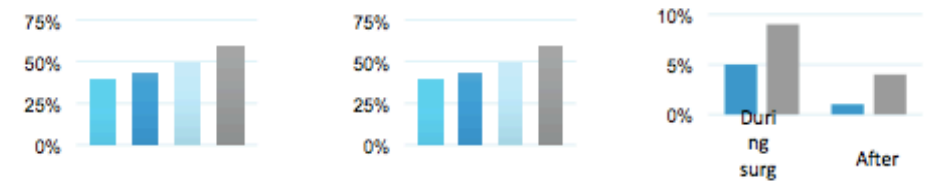
Patients with pCR with study treatment

- Group 1 - control: 42%
- Group 2 - bevacizumab: 50%
- Group 3 - carboplatin: 53%
- Group 4 - bevacizumab & carboplatin: 67%

Other results

The following results were not the main goal of the study. Researchers did not include enough people to get clear results. These results need more study.

Group 1 Group 2 Group 3 Group 4



pCR rates by treatment

Patients in Groups 2, 3 & 4 were more likely to have pCR in the breast and lymph nodes.

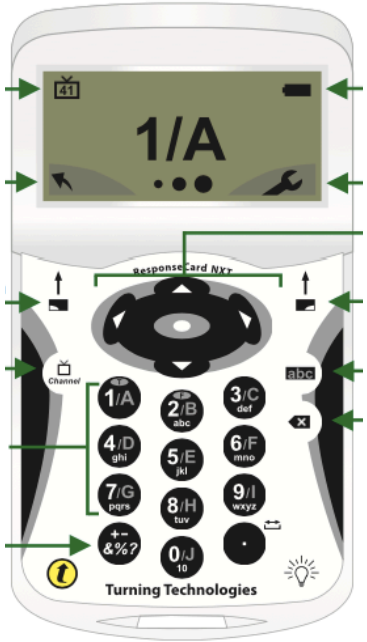
Less breast removed

Patients in Groups 2, 3 & 4 were more likely to have a lumpectomy after treatment.

Problems with surgery

Patients in Groups 2 & 4 were more likely to have surgery-related problems.

Now, it's YOUR turn:
9 questions



• ● ● The response is being sent.

• ● ✔ The response was sent successfully.

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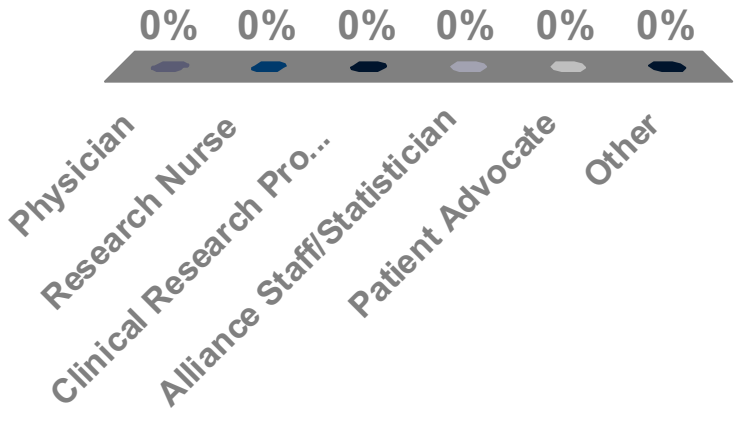
1. Please choose your role in the clinical trial system:

A. Physician
B. Research Nurse
C. Clinical Research Professional/Clinical Research Associate
D. Alliance Staff/Statistician
E. Patient Advocate
F. Other



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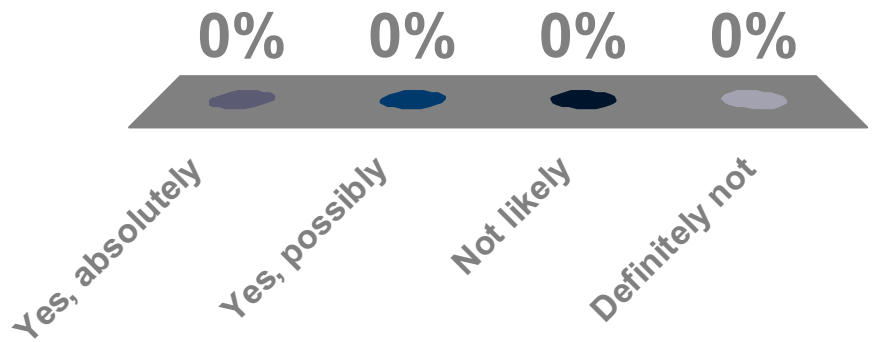
2. Are study result summaries (SRS) useful to patients?

A. Yes, absolutely
B. Yes, possibly
C. Not likely
D. Definitely not



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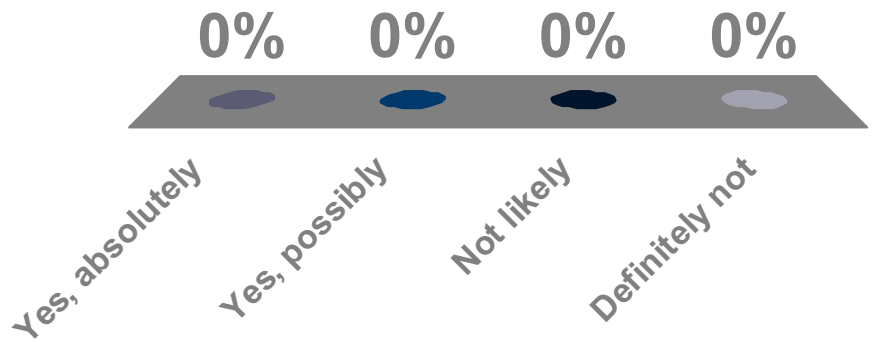
3. Are study result summaries (SRS) useful to you & your staff?

A. Yes, absolutely
B. Yes, possibly
C. Not likely
D. Definitely not



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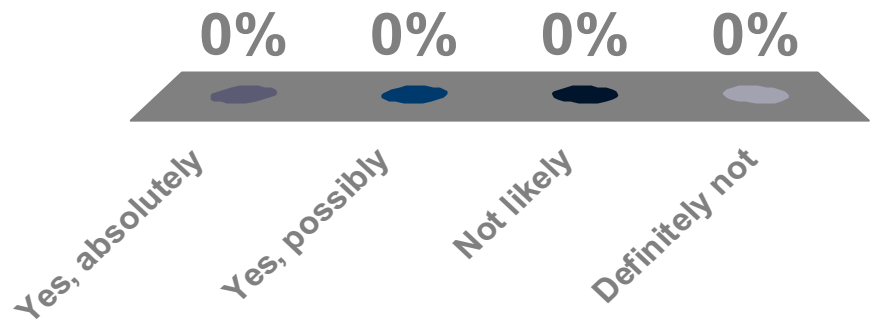
4. Would you use study result summaries (SRS) when a publication was released?

A. Yes, absolutely
B. Yes, possibly
C. Not likely
D. Definitely not



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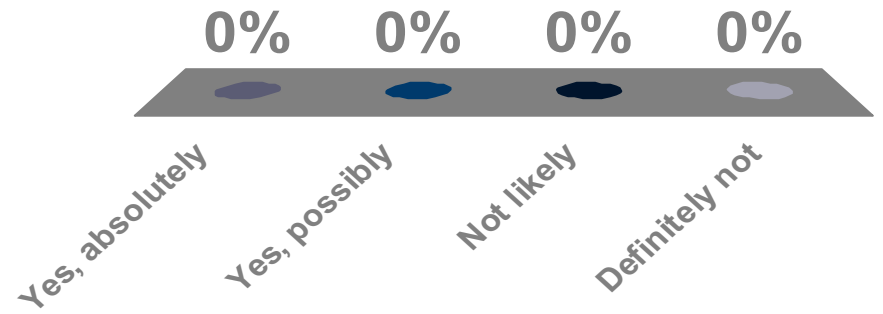
5. Would you use study result summaries (SRS) for routine/local media coverage?

A. Yes, absolutely
B. Yes, possibly
C. Not likely
D. Definitely not



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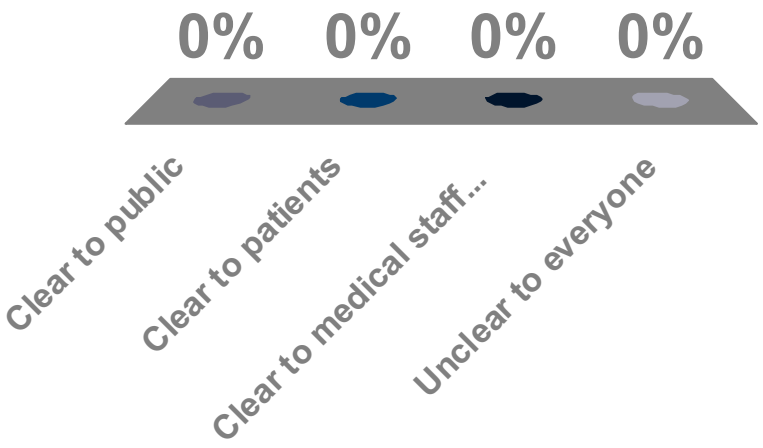
6. How clear is the study result summaries (SRS) information (new format)?

A. Clear to public
B. Clear to patients
C. Clear to medical staff only
D. Unclear to everyone



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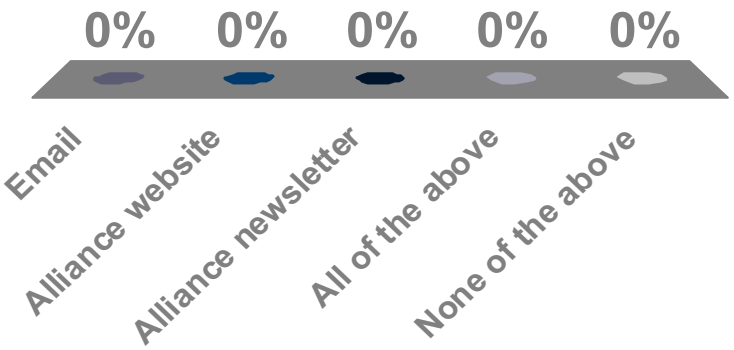
7. What would be the best way to distribute study result summaries (SRS) to you (select one)?

A. Email
B. Alliance website
C. Alliance newsletter
D. All of the above
E. None of the above



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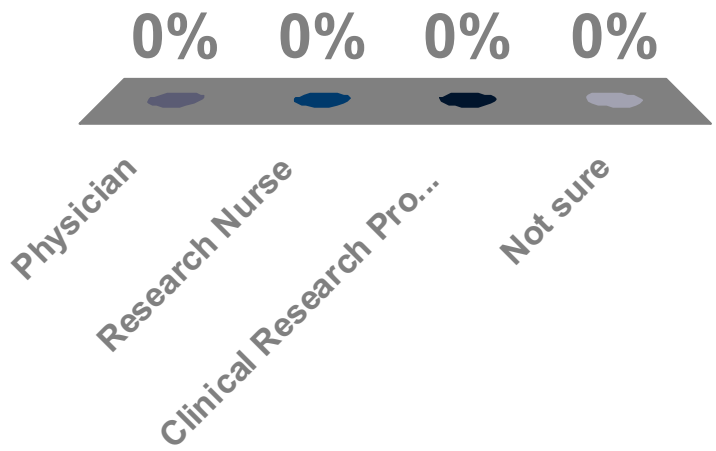
8. Who in your office would share study result summaries (SRS) with patients?

A. Physician
B. Research Nurse
C. Clinical Research Professional/Clinical Research Associate
D. Not sure



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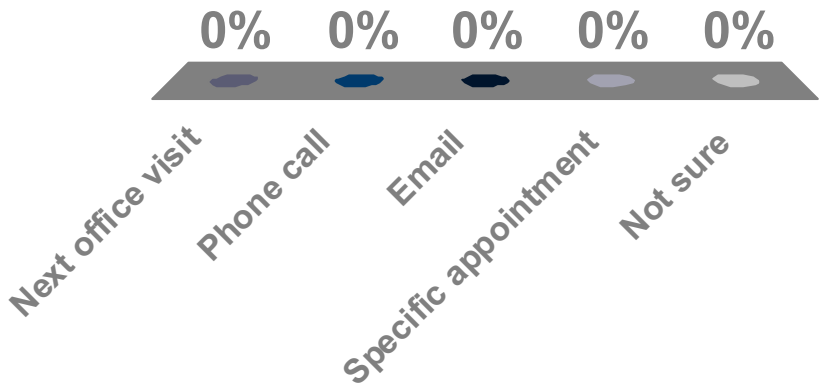
9. When and how will study result summaries (SRS) be shared with patients?

A. Next office visit
B. Phone call
C. Email
D. Specific appointment
E. Not sure



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Thank you for showing patients you care!

- 7 committees (Fall 2016)
- Analyze results
- Trial participant survey
- Look for funding (SWOG interested too)
- More input?
  - deborah@tumortime.com

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