How to Return Research Results to Patients and Families? The Children's Oncology Group Experience

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COG Educational Track at APHON, 2020

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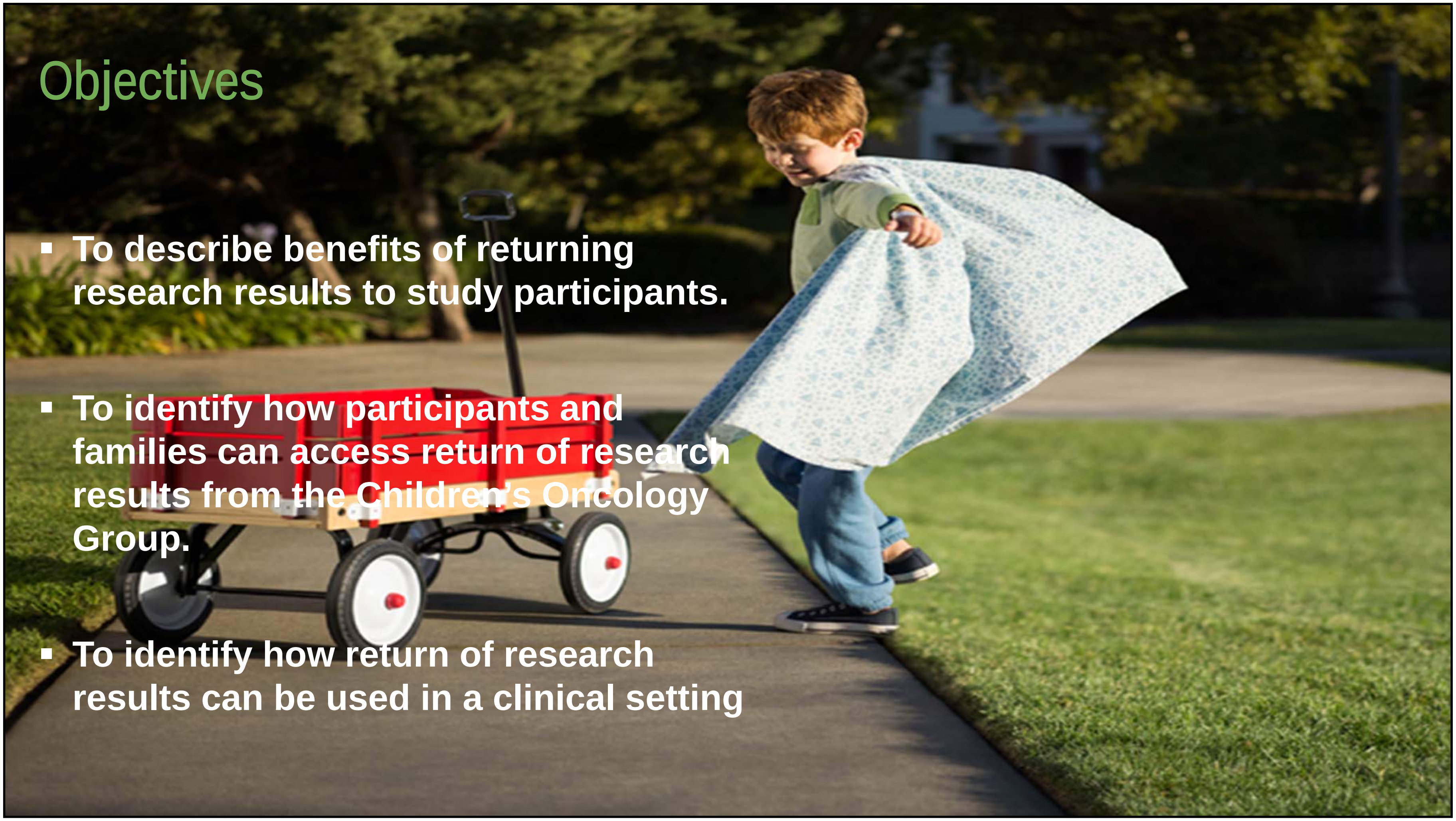
Disclosure

- Dr. Kim Pyke-Grimm has no industry relationships.
- Off label use will not be discussed.
- Currently, I am a Postdoctoral Fellow in Palliative Care at Stanford University supported by the Stanford University School of Nursing Alumnae.

COG Disclosure

The information in this presentation is intended for educational purposes only and is solely for the use of the individual nurse learner. This information is not intended as the sole source of guidance in providing Children's Oncology Group (COG) protocol-directed nursing care, and current COG protocols should always be consulted prior to making patient care decisions for any patient enrolled on a COG protocol. Learners should also be aware that COG protocols are research plans designed to investigate particular study questions, that recommendations for treatment and dosing are made within the context of specific research aims, and that these recommendations are intended only for use within a structured research setting. Although every attempt has been made to assure that the informational content contained herein is as accurate and complete as possible as of the date of presentation, no warranty or representation, express or implied, is made as to the accuracy, reliability, completeness, relevance, or timeliness of this content. This information may not be copied or redistributed in any form, or used for any purpose other than nursing education.



Objectives

- To describe benefits of returning research results to study participants.
- To identify how participants and families can access return of research results from the Children's Oncology Group.
- To identify how return of research results can be used in a clinical setting

Ethics & Return of Results

Beneficence

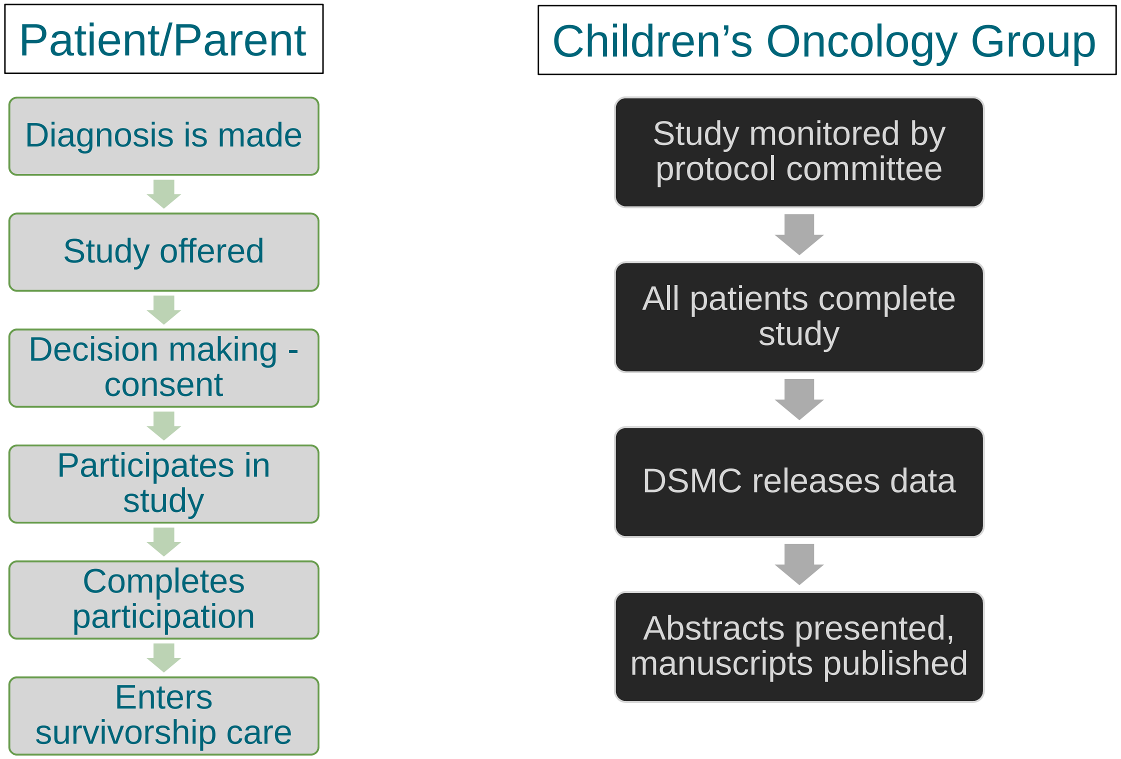
Autonomy

Veracity

Justice

Respect
for
People

The Research Experience

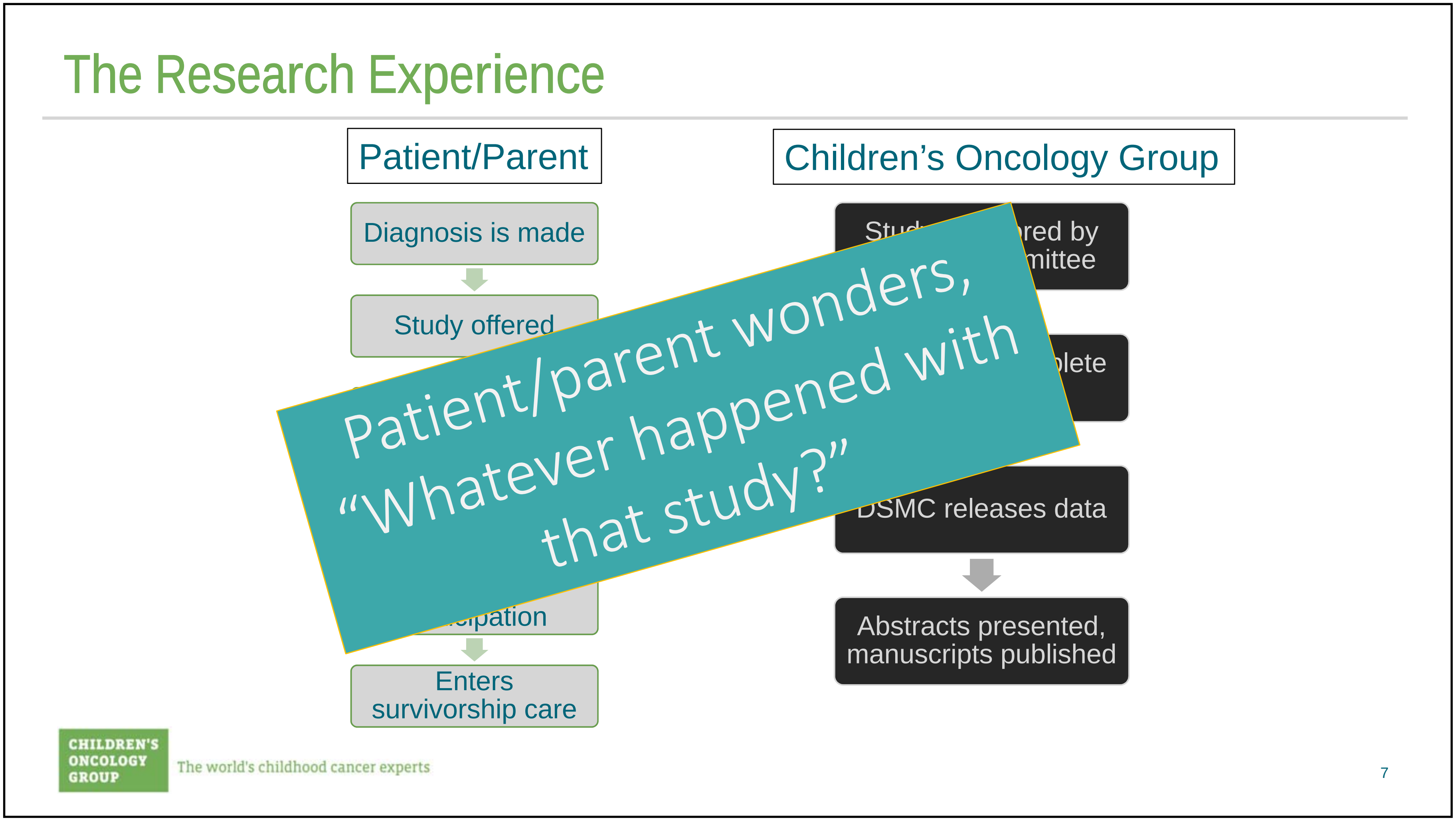


Patient/Parent

- Diagnosis is made
- Study offered
- Decision making - consent
- Participates in study
- Completes participation
- Enters survivorship care

Children’s Oncology Group

- Study monitored by protocol committee
- All patients complete study
- DSMC releases data
- Abstracts presented, manuscripts published



The Research Experience

Patient/Parent

Diagnosis is made

Study offered

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Enters survivorship care

Children’s Oncology Group

Stud red by mittee

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DSMC releases data

Abstracts presented, manuscripts published

Patient/parent wonders, “Whatever happened with that study?”

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Question

- Have any of your patients or families asked you about the results of the clinical trial they were enrolled in?

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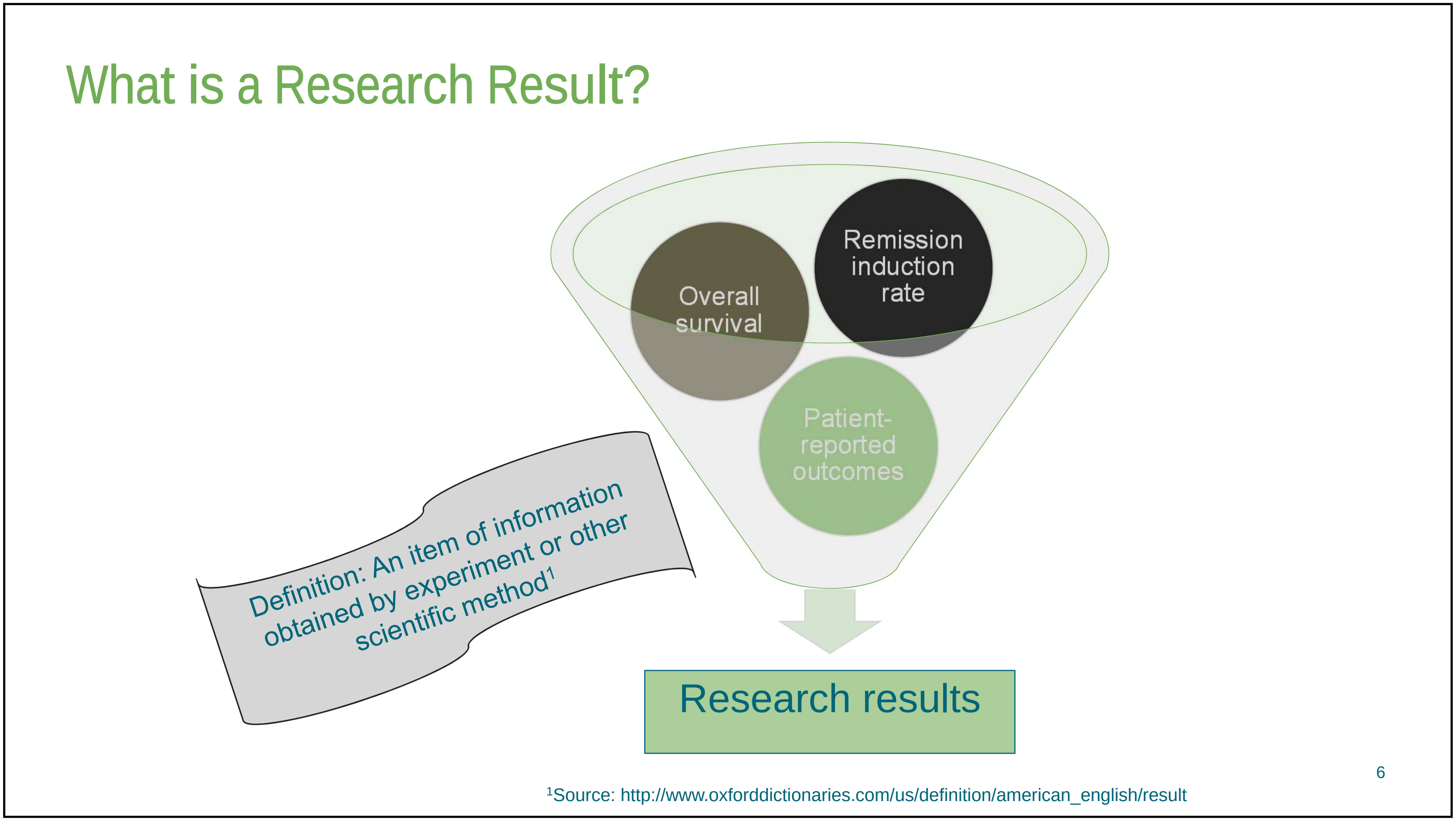


What is a Research Result?

Overall survival

Remission induction rate

Patient-reported outcomes

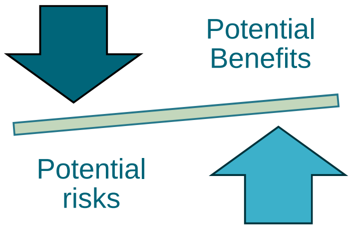
Research results

Definition: An item of information obtained by experiment or other scientific method[1]

[1]Source: http://www.oxforddictionaries.com/us/definition/american_english/result

Considerations in Returning Research Results

- Distress in revisiting diagnosis or death
- Misunderstanding of adverse information
- Anger or sadness about results describing unfavorable outcomes



Potential Benefits

Potential risks

- Participants' contribution to research recognized
- Participants feel valued and appreciated
- Results disseminated in a more accurate and nuanced way
- Information may be useful in decision-making
- Broader public understanding of social benefits of research

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Bubela et al. 2004; Moynihan et al. 2000; Fernandez et al. 2003; Partridge & Winer 2002; Miller et al. 2008; Schulz et al. 2003; Markman 2006; Fernandez et al. 2004

Clinical Trials

70% of all children with cancer in North America enroll in a COG clinical trial

Many RCTs compare current best-known treatment/intervention (standard arm) vs. experimental treatment/intervention

These studies include clinical trials (phases I-III)

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An Epidemiology Precedent

PEDIATRICS®
OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

Informing Subjects of Epidemiologic Study Results
Greta R. Bunin, Anne E. Kazak and Olga Mitelman
Pediatrics 1996;97;486

"It is valuable to many parents to receive information about results of research in which they have participated. We found little evidence of strong negative effects…"

COG Return of Results Task Force

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JOURNAL OF CLINICAL ONCOLOGY

SPECIAL ARTICLE

Recommendations for the Return of Research Results to Study Participants and Guardians: A Report From the Children's Oncology Group

Conrad V. Fernandez, Kathleen Ruccione, Robert J. Wells, Jay B. Long, Wendy Pelletier, Mary C. Hooke, Rebecca D. Pentz, Robert B. Noll, Justin N. Baker, Maura O'Leary, Gregory Reaman, Peter C. Adamson, and Steven Joffe

Conrad V. Fernandez, Izaak Walton Killam Health Centre, Dalhousie University, Halifax, Nova Scotia; Wendy Pelletier, Alberta Children's Hospital, Calgary, Alberta, Canada; Kathleen Ruccione, Children's Hospital Los Angeles, Los Angeles; Jay B. Long, Jonathan Jaques Children's Cancer, Miller Children's Hospital Long Beach, Long Beach, CA; Robert J. Wells, The University of Texas MD Anderson Cancer Center, Houston, TX; Mary C. Hooke, University of Minnesota School of Nursing, Minneapolis, MN; Rebecca D. Pentz, Emory University

Medical School, Boston, MA.

Submitted July 9, 2012; accepted September 17, 2012; published online ahead of print at www.jco.org on October 29, 2012.

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ABSTRACT

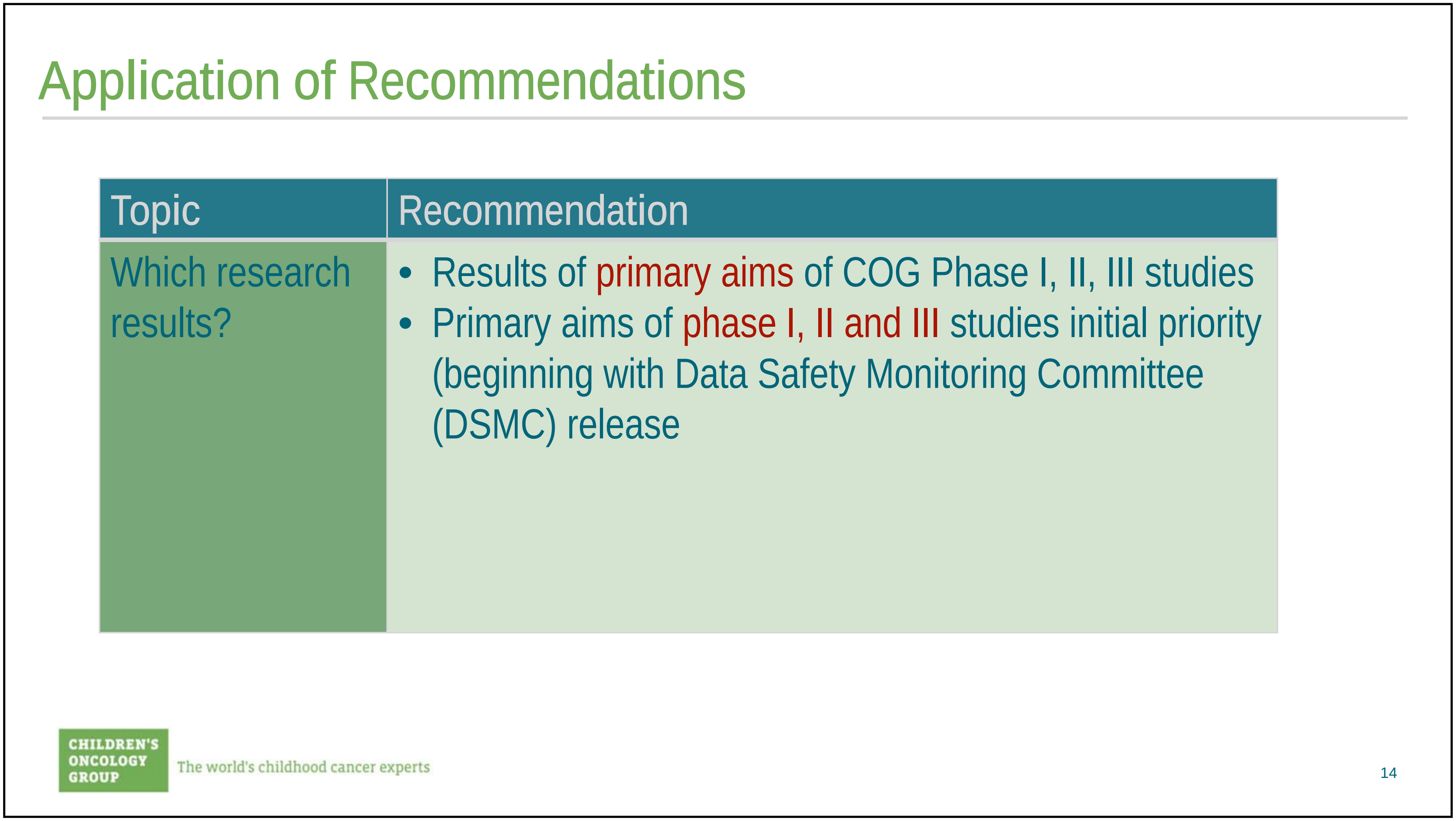
Purpose
The Children's Oncology Group (COG) strongly supports the widely recognized principle that research participants should be offered a summary of study results. The mechanism by which to do so in a cooperative research group setting has not been previously described.

Methods
On the basis of a review of the available empirical and theoretic literature and on iterative, multidisciplinary discussion, a COG Return of Results Task Force (RRTF) offered detailed

participants. They can be used by individual investigators, multi-investigator research collaboratives, and large cooperative groups.

J Clin Oncol 30:4573-4579. © 2012 by American Society of Clinical Oncology

Conclusion: These recommendations provide a framework for the offering and returning of results to participants. They can be used by individual investigators, multi-investigator research collaboratives, and large cooperative groups.



Application of Recommendations

Topic	Recommendation
Which research results?	• Results of primary aims of COG Phase I, II, III studies • Primary aims of phase I, II and III studies initial priority (beginning with Data Safety Monitoring Committee (DSMC) release

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Application of Recommendations

Topic	Recommendation
When (in scientific process) to offer results?	• Primary analyses: One year from DSMC release • Release with publication of primary findings manuscript

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Application of Recommendations

Topic	Recommendation
Who should be offered return of results (ROR)?	• Lay summary is offered to all participants • Summary openly accessible on COG website
When and how should participants first be offered ROR?	• Informed consent document • COG letter given at participant's study completion and/or in the LTFU clinic • At re-consent for minors reaching age of majority

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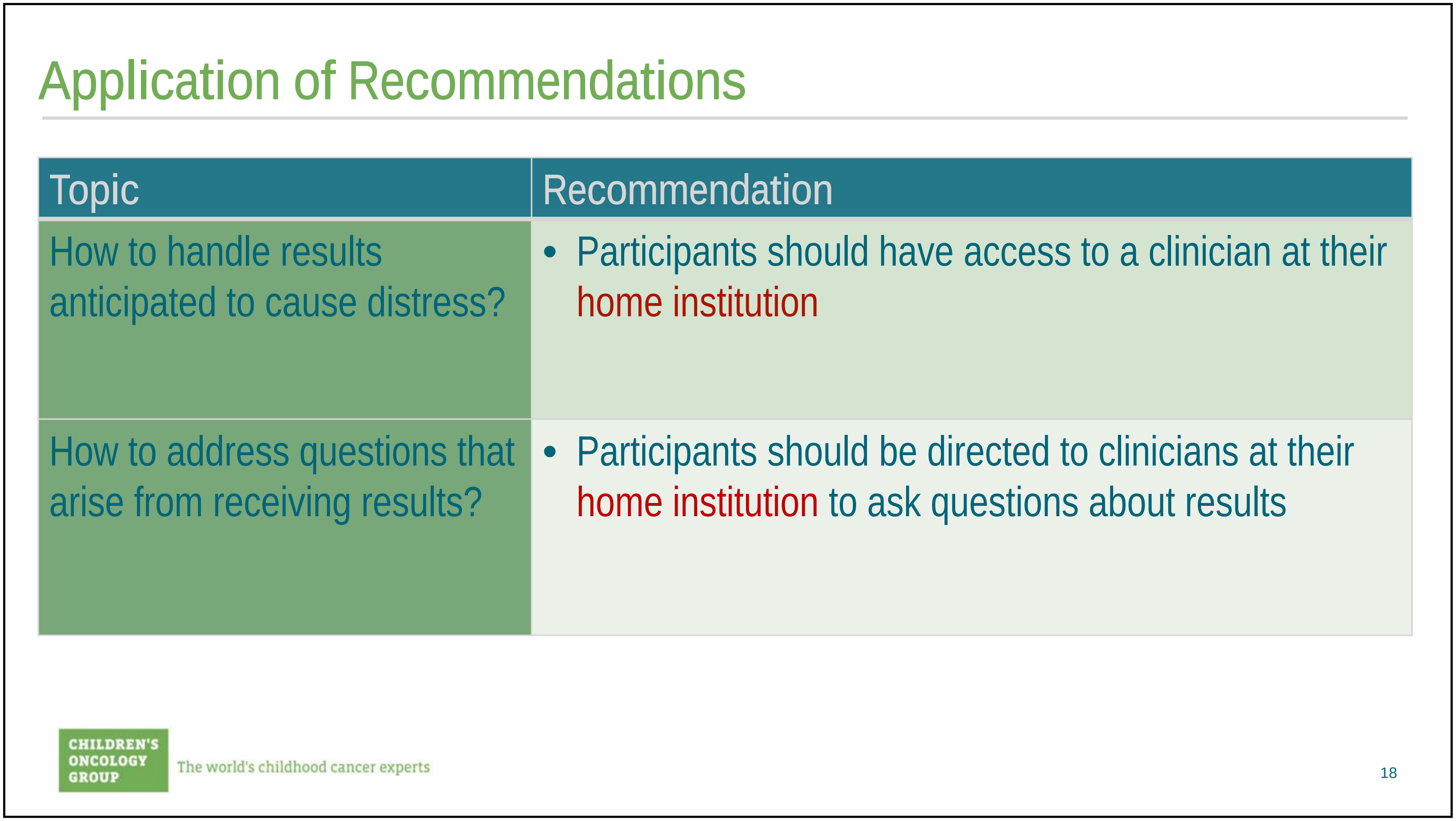
Application of Recommendations

Topic	Recommendation
How to disseminate lay summary?	• Register on COG public website for email notification (participant responsible for keeping contact info current) • In “accessible level” of English (local translation as needed) using a consistent template



Application of Recommendations

Topic	Recommendation
How to handle results anticipated to cause distress?	• Participants should have access to a clinician at their home institution
How to address questions that arise from receiving results?	• Participants should be directed to clinicians at their home institution to ask questions about results

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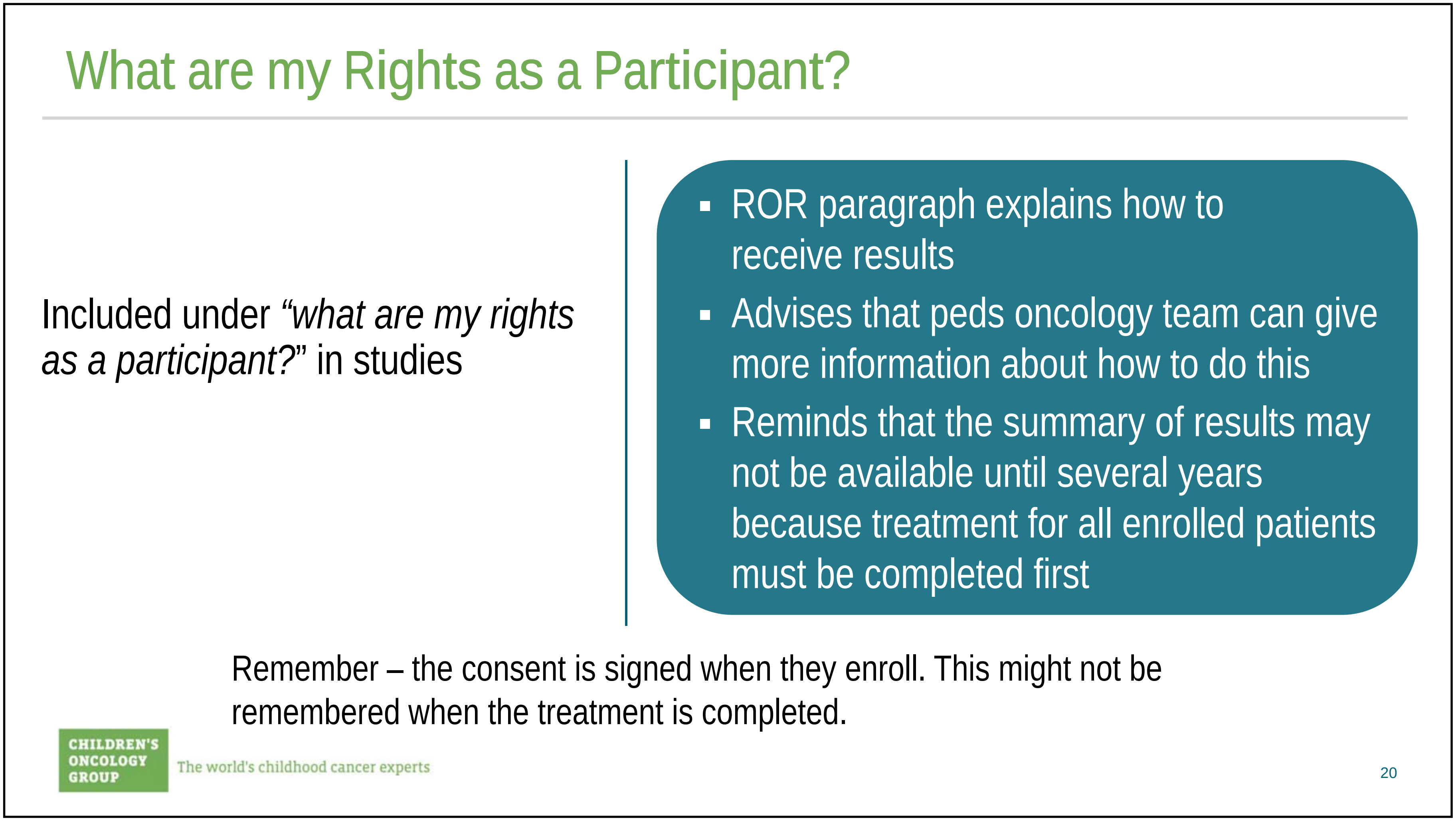
Application of Recommendations

Topic	Recommendation
What about legal and regulatory issues?	• Education of COG members and others about their roles and responsibilities r/t ROR
What follow-up research should be done?	• Evaluation of use and impact of the COG website in returning results to participants



What are my Rights as a Participant?

Included under *“what are my rights as a participant?”* in studies

- ROR paragraph explains how to receive results
- Advises that peds oncology team can give more information about how to do this
- Reminds that the summary of results may not be available until several years because treatment for all enrolled patients must be completed first

Remember – the consent is signed when they enroll. This might not be remembered when the treatment is completed.

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Language Embedded in Consents

What are my rights as a participant?

During your follow-up visits after treatment, you may ask to be given a summary of the study results, which will only be available after the study is fully completed. *A summary of the study results will also be posted on the Children's Oncology Group website ( ).* To receive the results, you may either (1) go to the COG website to check if results are available or (2) register your information with the COG on its web site and have an email sent to you when the results are available. Your pediatric oncology team from your hospital can give you additional instructions on how to do this. Please note, that the summary of results may not be available until several years after treatment for all people on the study is completed, and not only when you complete treatment.

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Consents

- Do you think that patients or families remember what they read in a consent?
- Do they keep a copy?
- Do they ask questions triggered by the consent form such as return of results?
- OR… is this just forgotten?

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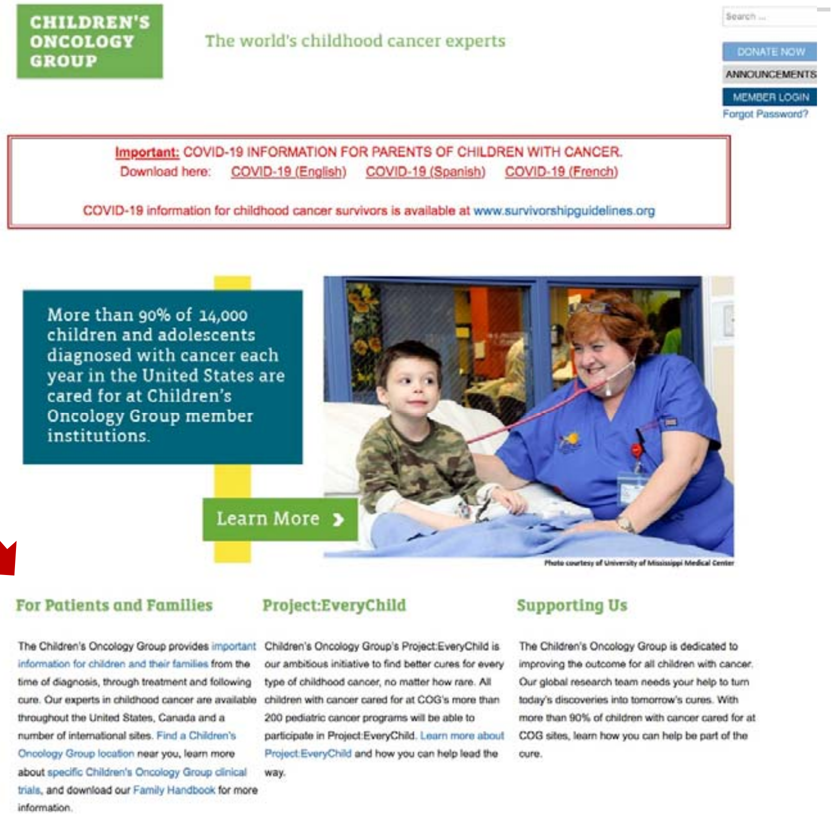
Case Study

Lawrence is an 8 year-old male who was diagnosed with Wilms tumor at 20 months of age. He was treated on AREN0532. He is being seen in long term follow-up clinic today and his parents ask, “what did the study show?”

You are his clinic nurse. What would you do?

Return of Results Website

- Do you know where the public COG website is?
- Do you know how to navigate to the Return of Results Webpage?



Important: COVID-19 INFORMATION FOR PARENTS OF CHILDREN WITH CANCER.
Download here: COVID-19 (English) COVID-19 (Spanish) COVID-19 (French)

COVID-19 information for childhood cancer survivors is available at www.survivorshipguidelines.org

More than 90% of 14,000 children and adolescents diagnosed with cancer each year in the United States are cared for at Children's Oncology Group member institutions.

Photo courtesy of University of Mississippi Medical Center

For Patients and Families

The Children's Oncology Group provides important information for children and their families from the time of diagnosis, through treatment and following cure. Our experts in childhood cancer are available throughout the United States, Canada and a number of international sites. Find a Children's Oncology Group location near you, learn more about specific Children's Oncology Group clinical trials, and download our Family Handbook for more information.

Project:EveryChild

Children's Oncology Group's Project:EveryChild is our ambitious initiative to find better cures for every type of childhood cancer, no matter how rare. All children with cancer cared for at COG's more than 200 pediatric cancer programs will be able to participate in Project:EveryChild. Learn more about Project:EveryChild and how you can help lead the way.

Supporting Us

The Children's Oncology Group is dedicated to improving the outcome for all children with cancer. Our global research team needs your help to turn today's discoveries into tomorrow's cures. With more than 90% of children with cancer cared for at COG sites, learn how you can help be part of the cure.

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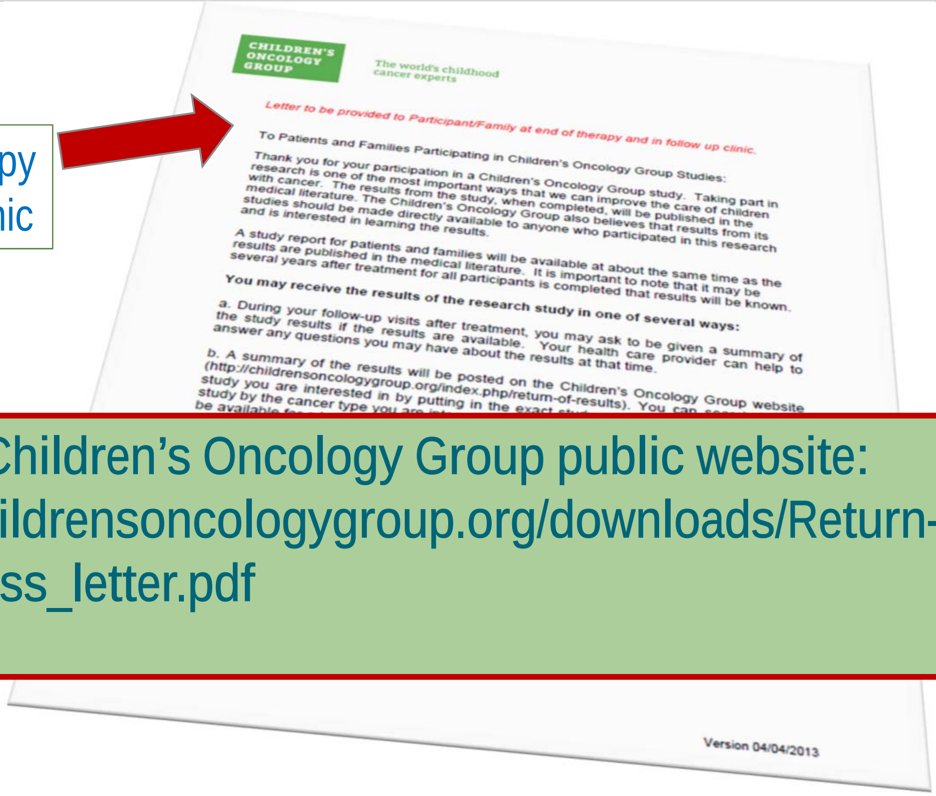
Letter to Participant/Family

At end of therapy in follow-up clinic



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Letter to be provided to Participant/Family at end of therapy and in follow up clinic.

To Patients and Families Participating in Children's Oncology Group Studies:

Thank you for your participation in a Children's Oncology Group study. Taking part in research is one of the most important ways that we can improve the care of children with cancer. The results from the study, when completed, will be published in the medical literature. The Children's Oncology Group also believes that results from its studies should be made directly available to anyone who participated in this research and is interested in learning the results.

A study report for patients and families will be available at about the same time as the results are published in the medical literature. It is important to note that it may be several years after treatment for all participants is completed that results will be known.

You may receive the results of the research study in one of several ways:

a. During your follow-up visits after treatment, you may ask to be given a summary of the study results if the results are available. Your health care provider can help to answer any questions you may have about the results at that time.

b. A summary of the results will be posted on the Children's Oncology Group website (http://childrensoncologygroup.org/index.php/return-of-results). You can
study you are interested in by putting in the exact
study by the cancer type you are
be available

Version 04/04/2013

Available on Children's Oncology Group public website: http://www.childrensoncologygroup.org/downloads/Return-of-Results_Access_letter.pdf

Website Registration for RORs

Step 1

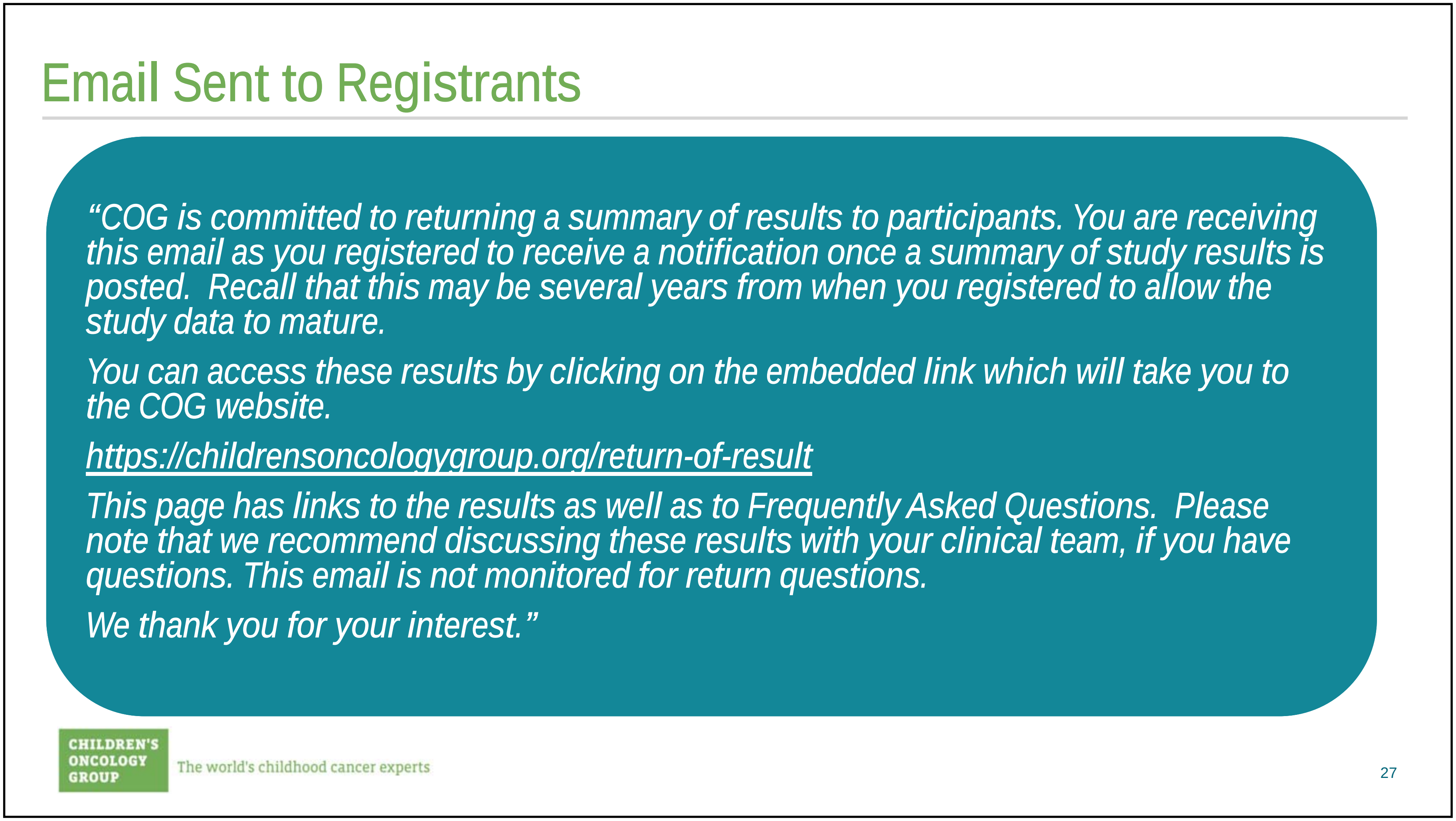
- The patient/family or interested member of the public registers their email associated with a particular study.

Step 2

- Registrant is notified that they are responsible for keeping email contact up to date.

Step 3

- Once a new lay summary is posted to the website, an automatic notification email is sent to all those who register.



Email Sent to Registrants

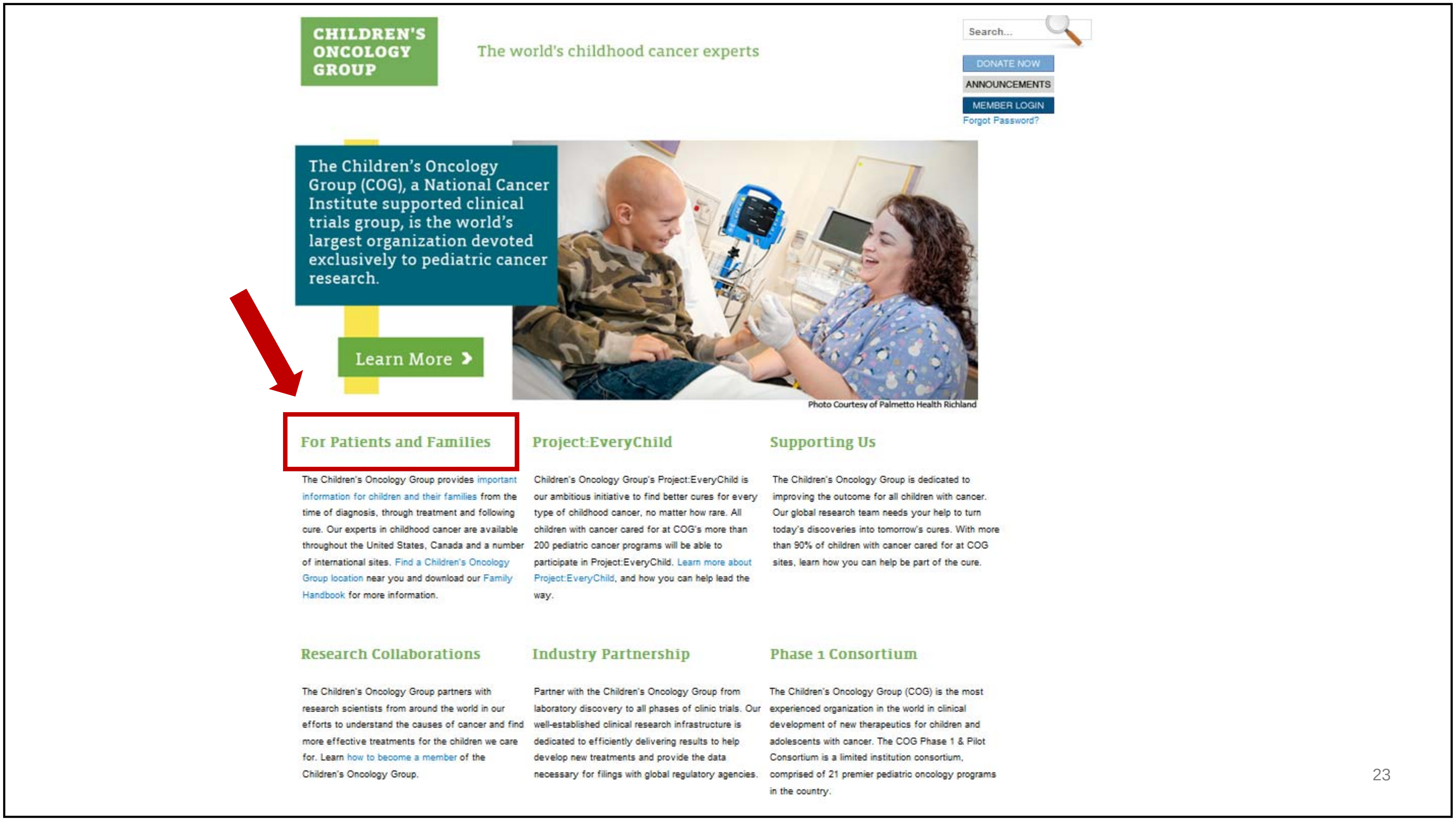
“COG is committed to returning a summary of results to participants. You are receiving this email as you registered to receive a notification once a summary of study results is posted. Recall that this may be several years from when you registered to allow the study data to mature.

You can access these results by clicking on the embedded link which will take you to the COG website.

https://childrensoncologygroup.org/return-of-result

This page has links to the results as well as to Frequently Asked Questions. Please note that we recommend discussing these results with your clinical team, if you have questions. This email is not monitored for return questions.

We thank you for your interest.”



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The Children's Oncology Group (COG), a National Cancer Institute supported clinical trials group, is the world's largest organization devoted exclusively to pediatric cancer research.

Photo Courtesy of Palmetto Health Richland

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Research Collaborations

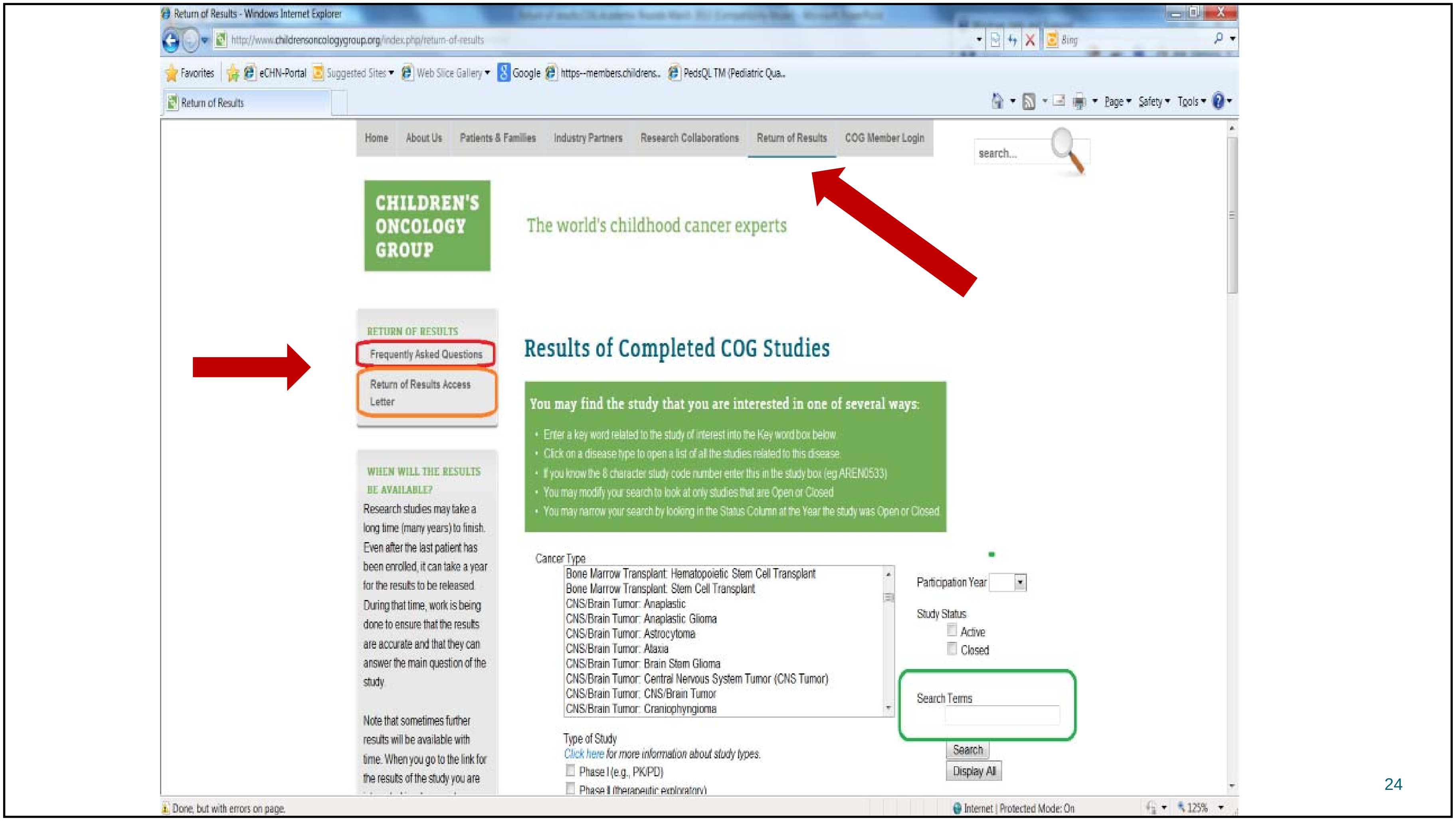
The Children's Oncology Group partners with research scientists from around the world in our efforts to understand the causes of cancer and find more effective treatments for the children we care for. Learn how to become a member of the Children's Oncology Group.

Industry Partnership

Partner with the Children's Oncology Group from laboratory discovery to all phases of clinic trials. Our well-established clinical research infrastructure is dedicated to efficiently delivering results to help develop new treatments and provide the data necessary for filings with global regulatory agencies.

Phase 1 Consortium

The Children's Oncology Group (COG) is the most experienced organization in the world in clinical development of new therapeutics for children and adolescents with cancer. The COG Phase 1 & Pilot Consortium is a limited institution consortium, comprised of 21 premier pediatric oncology programs in the country.



WHEN WILL THE RESULTS BE AVAILABLE?

Research studies may take a long time (many years) to finish. Even after the last patient has been enrolled, it can take a year for the results to be released. During that time, work is being done to ensure that the results are accurate and that they can answer the main question of the study.

Note that sometimes further results will be available with time. When you go to the link for the results of the study you are

Results of Completed COG Studies

You may find the study that you are interested in one of several ways:

- Enter a key word related to the study of interest into the Key word box below
- Click on a disease type to open a list of all the studies related to this disease.
- If you know the 6 character study code number enter this in the study box (eg AREN0533)
- You may modify your search to look at only studies that are Open or Closed
- You may narrow your search by looking in the Status Column at the Year the study was Open or Closed

Cancer Type

Bone Marrow Transplant: Hematopoietic Stem Cell Transplant
Bone Marrow Transplant: Stem Cell Transplant
CNS/Brain Tumor: Anaplastic
CNS/Brain Tumor: Anaplastic Glioma
CNS/Brain Tumor: Astrocytoma
CNS/Brain Tumor: Ataxia
CNS/Brain Tumor: Brain Stem Glioma
CNS/Brain Tumor: Central Nervous System Tumor (CNS Tumor)
CNS/Brain Tumor: CNS/Brain Tumor
CNS/Brain Tumor: Craniopharyngioma

Type of Study

Click here for more information about study types.

☐ Phase I (e.g., PK/PD)
☐ Phase II (therapeutic exploratory)

ROR Website Search Options

- ✓ Search by study number
- ✓ Search by cancer type
- ✓ Search in cancer type (identified by name, number, or years open)

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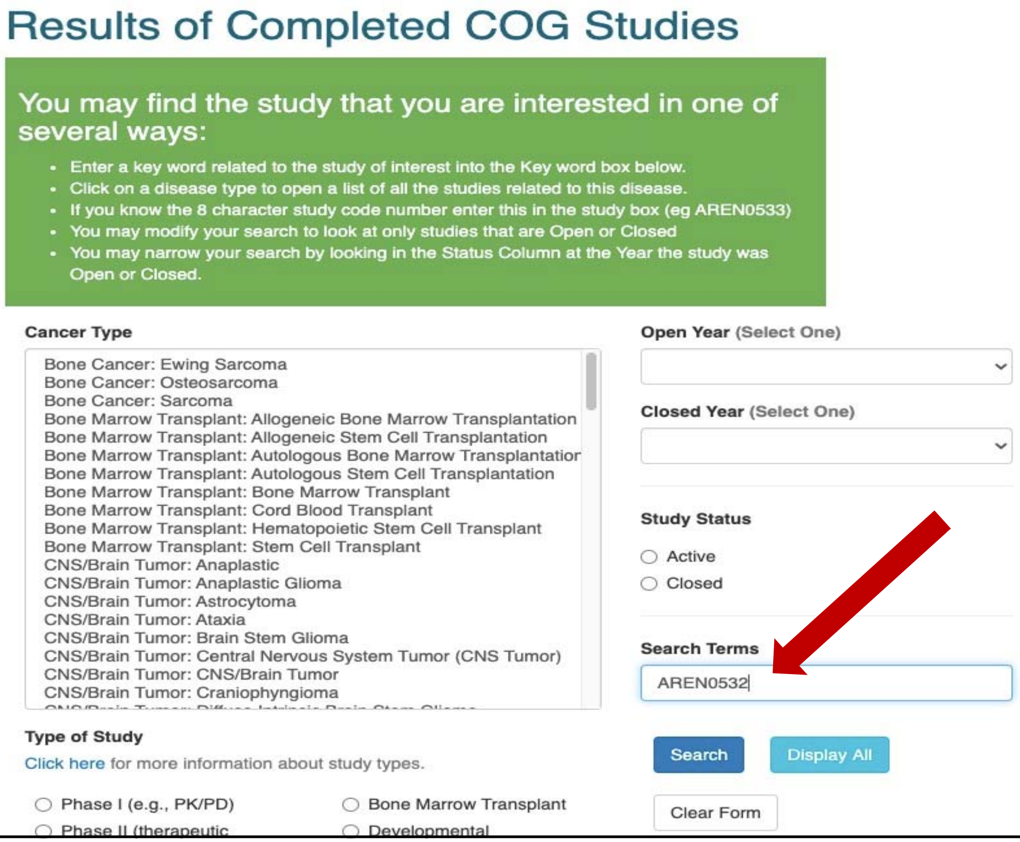
Searching for AREN0532



Results of Completed COG Studies

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- You may modify your search to look at only studies that are Open or Closed
- You may narrow your search by looking in the Status Column at the Year the study was Open or Closed.

Cancer Type

Bone Cancer: Ewing Sarcoma
Bone Cancer: Osteosarcoma
Bone Cancer: Sarcoma
Bone Marrow Transplant: Allogeneic Bone Marrow Transplantation
Bone Marrow Transplant: Allogeneic Stem Cell Transplantation
Bone Marrow Transplant: Autologous Bone Marrow Transplantatior
Bone Marrow Transplant: Autologous Stem Cell Transplantation
Bone Marrow Transplant: Bone Marrow Transplant
Bone Marrow Transplant: Cord Blood Transplant
Bone Marrow Transplant: Hematopoietic Stem Cell Transplant
Bone Marrow Transplant: Stem Cell Transplant
CNS/Brain Tumor: Anaplastic
CNS/Brain Tumor: Anaplastic Glioma
CNS/Brain Tumor: Astrocytoma
CNS/Brain Tumor: Ataxia
CNS/Brain Tumor: Brain Stem Glioma
CNS/Brain Tumor: Central Nervous System Tumor (CNS Tumor)
CNS/Brain Tumor: CNS/Brain Tumor
CNS/Brain Tumor: Craniophyngioma

Type of Study

Click here for more information about study types.

○ Phase I (e.g., PK/PD) ○ Bone Marrow Transplant
○ Phase II (therapeutic ○ Developmental

Open Year (Select One)

Closed Year (Select One)

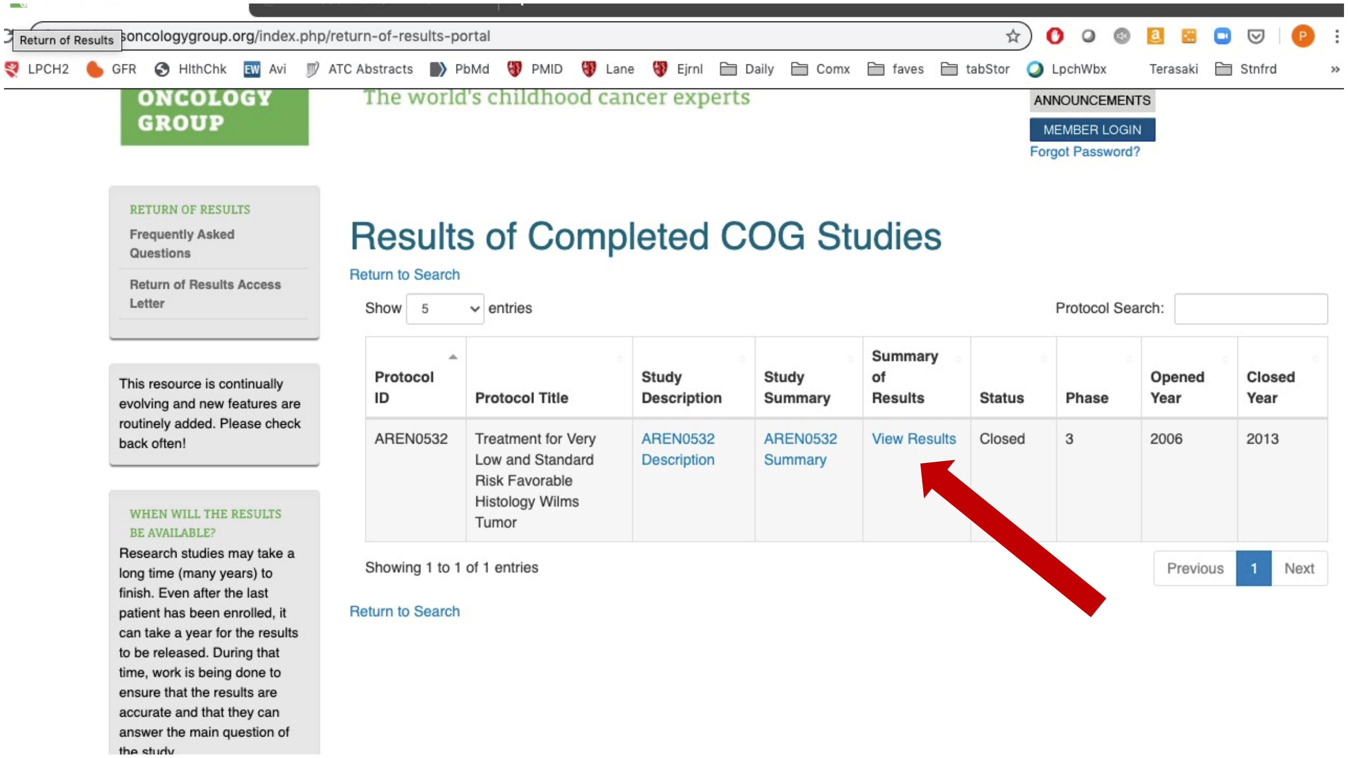
Study Status

○ Active
○ Closed

Search Terms

AREN0532

Searching for AREN0532



This resource is continually evolving and new features are routinely added. Please check back often!

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Results of Completed COG Studies

Return to Search

Show 5 entries

Protocol Search:

Protocol ID	Protocol Title	Study Description	Study Summary	Summary of Results	Status	Phase	Opened Year	Closed Year
AREN0532	Treatment for Very Low and Standard Risk Favorable Histology Wilms Tumor	AREN0532 Description	AREN0532 Summary	View Results	Closed	3	2006	2013

Showing 1 to 1 of 1 entries

Return to Search

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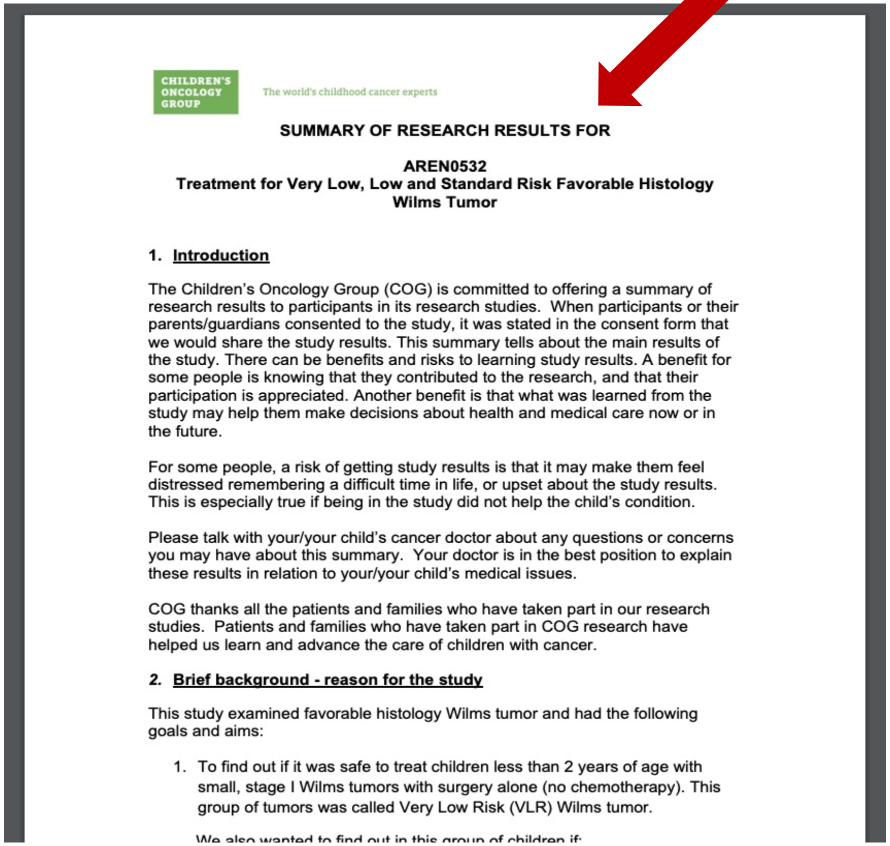
Summary for AREN0532



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SUMMARY OF RESEARCH RESULTS FOR

AREN0532
Treatment for Very Low, Low and Standard Risk Favorable Histology Wilms Tumor

1. Introduction

The Children's Oncology Group (COG) is committed to offering a summary of research results to participants in its research studies. When participants or their parents/guardians consented to the study, it was stated in the consent form that we would share the study results. This summary tells about the main results of the study. There can be benefits and risks to learning study results. A benefit for some people is knowing that they contributed to the research, and that their participation is appreciated. Another benefit is that what was learned from the study may help them make decisions about health and medical care now or in the future.

For some people, a risk of getting study results is that it may make them feel distressed remembering a difficult time in life, or upset about the study results. This is especially true if being in the study did not help the child's condition.

Please talk with your/your child's cancer doctor about any questions or concerns you may have about this summary. Your doctor is in the best position to explain these results in relation to your/your child's medical issues.

COG thanks all the patients and families who have taken part in our research studies. Patients and families who have taken part in COG research have helped us learn and advance the care of children with cancer.

2. Brief background - reason for the study

This study examined favorable histology Wilms tumor and had the following goals and aims:

1. To find out if it was safe to treat children less than 2 years of age with small, stage I Wilms tumors with surgery alone (no chemotherapy). This group of tumors was called Very Low Risk (VLR) Wilms tumor.

We also wanted to find out in this group of children if:

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COG ROR Lay Summary Process

DSMC release of study data → *Communication & Publications process

↓

Notification of Nurse Liaison for RORs who assigns study to Summary Subcommittee Member

↓

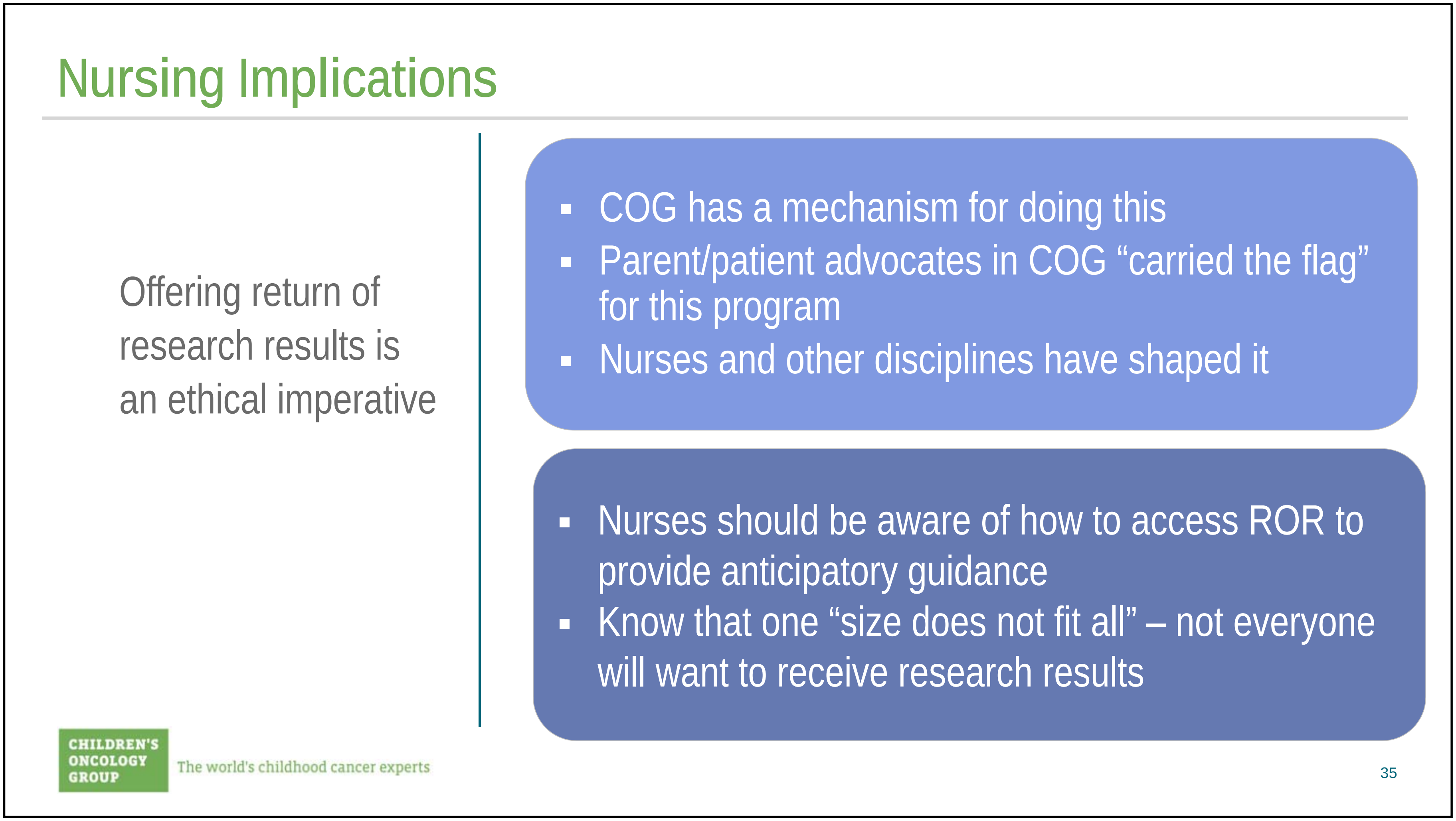
Study Chair, DCN, Study Nurse, Study statistician & PAC member develop and approve ROR lay summary

↓

Final version to ROR Committee Co- chairs, COG Statistician & COG Chair

↓

ROR lay summary posted on COG website after DSMC release and primary findings are published



Nursing Implications

Offering return of research results is an ethical imperative

- COG has a mechanism for doing this
- Parent/patient advocates in COG “carried the flag” for this program
- Nurses and other disciplines have shaped it

- Nurses should be aware of how to access ROR to provide anticipatory guidance
- Know that one “size does not fit all” – not everyone will want to receive research results

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Thank you!

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