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Overview

Miami Cancer Institute
BAPTIST HEALTH SOUTH FLORIDA

The **Pediatric Cancer Clinical Trials Learn Guide** is designed to help support patients and their families as they face the challenges of their cancer journey.

This guide is interactive and serves as a creatively driven resource developed to support, educate and empower both patients, and their caregivers.

Here are a few ways that this guide can be used as an ongoing resource:

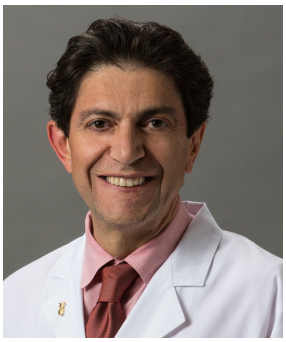
•Parts 1-2 include an overview of clinical trials to introduce you to what they are and help you to understand whether participating in a clinical trial might be right for your child. These sections feature Dr. Doured Daghistani and Teresa Reyersbach, RN.

•Parts 3-6 explain how clinical trials are created, and outline in detail the clinical trials at MCI, introducing the members of the clinical trial team and going over the steps of the clinical trial process. These sections feature Dr. Doured Daghistani and Teresa Reyersbach, RN.

•Part 7 explores the future of clinical trials and the latest advances in cancer treatment and research. This section features Dr. Minesh Mehta, and Dr. Doured Daghistani.

We suggest that you bring your ebook of this guide to meetings with Healthcare Professionals. You can get the ebook from the "**Request this EBook**" button above and will then be able to use it on your phone, tablet, computer, or print it out on paper.

Introducing Dr. Daghistani



Doured Daghistani, M.D.

Pediatric hematologist/oncologist **Doured Daghistani, M.D.**, has been elected vice president of the more than 1,400 physicians on the Baptist Hospital medical staff. He served as secretary/treasurer from 2008-2011. He also serves as medical director of pediatric oncology, and chairman of Baptist Children's Hospital Executive Board. He has been on staff at Baptist Hospital since 1992.

Dr. Daghistani received his medical degree from the University of Damascus, Syria, and completed his residency and fellowship at the University of Miami.

*"My name is **Doured Daghistani**, I am the Medical Director of Pediatric Oncology at the Miami Cancer Institute. I have been caring for children with cancer for over 30 years. I am the Principal Investigator of the Pediatric Oncology Department at the Miami Cancer Institute, and that means, I am the person responsible for choosing the best clinical trial based on the type of cancer that patient has."*

Dr. Daghistani is Board-certified in pediatrics with a subspecialty in pediatric hematology/oncology.

Introducing Teresa Reyersbach, RN

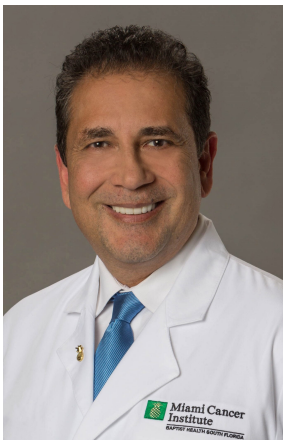
Teresa Reyersbach, RN

Teresa Reyersbach has worked for Baptist Health South Florida for the last 12 years. She earned her Bachelor of Science in Nursing (BSN) from Florida International University in 1987 and has worked in pediatric oncology for the last 28 years. During that time, Teresa delivered direct patient care in both inpatient and outpatient pediatric hematology/oncology clinical settings. Over the past 18 years, her focus has shifted towards pediatric oncology research as a research nurse.

*"Hi, my name is **Teresa Reyersbach** and I'm a Registered Nurse and the Clinical Research Associate for the Pediatric Clinical Trials available at Miami Cancer Institute."*

Most recently, Teresa has been working with members of the pediatric oncology team, coordinating the pediatric research that is available at Miami Cancer Institute.

Introducing Dr. Mehta



Minesh Mehta, M.D.

As deputy director and chief of radiation oncology, **Minesh Mehta, M.D.**, a world-renowned expert in radiation oncology, proton therapy and cancer research, will position Miami Cancer Institute's proton therapy center—the only one of its kind in South Florida and one of fewer than two dozen in the United States—as the region's top destination for this cutting-edge treatment. In March 2015, Baptist Health South Florida signed an agreement with IBA, the world's leading provider of proton therapy solutions for the treatment of cancer, to bring the advanced therapy to the Cancer Institute.

Dr. Mehta joins Baptist Health from the University of Maryland School of Medicine, where he served as medical director of the Maryland Proton Treatment Center in Baltimore and as the university's associate director of clinical research in the Department of Radiation Oncology. He previously held major academic, research and administrative leadership positions at Northwestern University in Chicago and the University of Wisconsin in Madison.

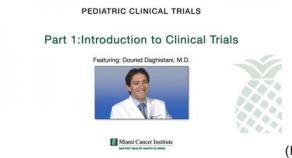
At the Robert H. Lurie Comprehensive Cancer Center of Northwestern University, **Dr. Mehta** was co-director of the Radiation Oncology Residency Training Program, mentoring many young physicians who have gone on to become prominent leaders in the field. He has designed and led numerous national and international clinical studies, receiving National Cancer Institute and National Institutes of Health grants and winning several honors for his research in brain and central nervous system tumors.

Dr. Mehta graduated with the highest honors from the University of Zambia School of Medicine. He completed his residency at the University of Wisconsin, where he'd go on to head its brain tumor program for more than 15 years.

Introduction

Part 1: Introduction to Clinical Trials

The Role of a Clinical Trial in Improving Cancer Outcomes



(https://vimeo.com/175172423)

Dr. Daghistani, *"I remember when I was a six year old child in 1965. I saw a movie where the doctor told the parents of a child who had acute leukemia, 'You have six months to enjoy with your child, because your child is going to die.' Now, I am proud to tell the parents that any child who has acute leukemia has an 80% to 90% chance of long-term survival."*

Without the clinical trials, we could not have reached the percentage of the long-term survival that we have right now.

To Learn More:
- More Information on Children's Cancer Research (https://childrensoncologygroup.org/index.php/research)

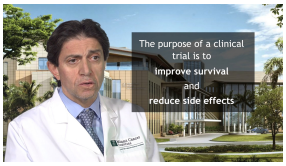
What is a Clinical Trial?

A clinical trial is a set of instructions on how to treat a patient. It may be testing a particular drug. In this example, we'll call that "Drug A". The trial tests how Drug A works when delivered in a particular fashion to a patient, whether that be oral or intravenous, whether it's given on a certain day of treatment, etc. The clinical trial has a certain set of instructions, and those instructions become known as a protocol. The protocol has every aspect that the treating physician and the hospital need to know.

Think of a clinical trial as a way of asking a particular question and then providing the institution, the researchers, and the physician with a set of detailed instructions on how to carry out the trial, so that every institution that is doing the clinical trial does it the same way and we can therefore measure the impact of the treatment of Drug A and see if that created an improvement in the outcome.

To Learn More:
- Information on Clinical Trials from the National Cancer Institute (http://www.cancer.gov/about-cancer/treatment/clinical-trials)
- Clinical Trials at the Children's Oncology Group (https://www.childrensoncologygroup.org/index.php/what-is-a-clinical-trial)

What is the Purpose of a Clinical Trial?



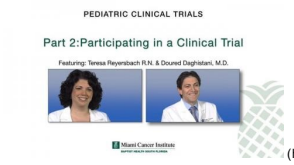
A clinical trial is a plan or a roadmap for treatment. The purpose of it is to improve the cancer survival and decrease the complication of the treatment. If you want to contribute to advancing cancer treatment in the future, sign up to participate in a clinical trial.

To Learn More:
- The Impact of COG's Research (https://childrensoncologygroup.org/index.php/home/62-about-us/about-us)

Participation

Part 2: Participating in a Clinical Trial

Selecting the Appropriate Trial for a Child



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To be eligible for a trial, means you meet the requirements for that specific study.

This can include such things as:

- Specific diagnosis
- Extent of disease or staging
- Age at diagnosis

Your physician will look at several factors to determine your child's eligibility before enrolling them in a clinical trial. A few of the things they will look at are the patient's diagnosis, how it has spread throughout other organs, the overall health of organ function, as well as the patient's willingness to participate in the clinical trial.

Is Participation Voluntary?

Participation in clinical trials is voluntary. Patients who decide not to participate will receive the best standard of care, there will be no negative reaction towards your child.

The Benefits of Participating

The benefits to your child of going into a clinical trial are that it allows us to give them the most up-to-date and advanced treatment plan that we can give them. In a standardized way, it allows us to evaluate whether the new treatment, the new drug, the new combination, the new timing in how the drugs are given actually amounts to any improvement in outcome.

We know that we would never have achieved the standard that we have today without previous children having gone into clinical trials. Therefore, it is a short-term gain for a particular child that provides a long-term gain for all children. Today, we are living on the backs of the children who came before us, and we are appreciative of what's happened to them, but we have also shown them that each time we finish a clinical trial the outcomes improve. That's our goal – to do what we can to give the best treatment to your child.

Parents sometimes ask, "What can I do to give my child the best opportunity for a cure?" We absolutely believe that going on a clinical trial gives the child the best chance, because then we are doing treatment in a way that is standardized, is rigorous, and has been overseen by a larger collective.

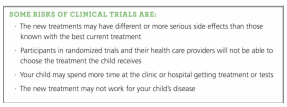
To Learn More:

- Impacts of COG's Clinical Trials Research (https://childrensoncologygroup.org/index.php/home/62-about-us/about-us)
- Possible Benefits and Risks In Clinical Trials (http://www.cancer.gov/about-cancer/treatment/clinical-trials/taking-part)

Risks in Participating

The risk to your child if they participate is that there may be unknown, unanticipated side effects that may affect their quality of life and may put them at risk. However, in

the design of the trial, these potential side effects have been thought out to great effect, and we optimize the trial mechanism to make sure that the child is safe.



To Learn More:

- Information on International Review Boards and Data & Safety Monitoring Boards (http://www.cancer.gov/about-cancer/treatment/clinical-trials/patient-safety/scientific-review)

Risks in not Participating

Often we're asked by parents "what are the risks to my child if they do not participate?" Sometimes they just cannot use certain drugs, because there are drugs that we are testing that the FDA (Food & Drug Administration) will not release to children who are not on clinical trials. We also cannot in good faith put a child on a treatment plan that is experimental in nature, meaning that we don't know what the long-term outcome or toxicities will be. Whenever someone chooses not to go on a clinical trial, we give them the best practices that we know today.

COG

Part 3: Creating Pediatric Clinical Trials

In the United States, the largest and most effective group treating kids with cancer using clinical trials is called the Children's Oncology Group, also known as COG. COG is funded by the National Cancer Institute and is the largest clinical trials group for children in the world. It has the greatest results and has brought together the most pre-eminent oncologists from around the country and the world to focus on a particular disease type and to bring their discoveries to the many hospitals that are its members.

(https://vimeo.com/170542488)

To Learn More:
- About the Children's Oncology Group (https://childrensoncologygroup.org/index.php/aboutus)

COG's Role In Creating Pediatric Clinical Trials

COG's role in pediatric clinical trials is to be the comprehensive organization that brings together many types of trial opportunities to patients. Whether it be a registration trial, a biology section, or therapeutics, treatment or long-term and survivorship trials, COG makes sure it's available to as many patients as possible.

To Learn More:
- Information On Different Types of Clinical Trials (http://www.cancer.gov/about-cancer/treatment/clinical-trials/what-are-trials/types)

Creating a Network for Effective Clinical Trials

Why is Collaborative Research Important?

While nearly 12,500 children and adolescents are diagnosed with cancer each year, there are many different kinds of children's cancer. When divided into the specific cancer types, the number of children with each is relatively small. In research, large numbers of patients are critical to ensuring that study results are meaningful. By enrolling patients from many hospitals in the same trial, the results become statistically significant. The approach is called collaborative research and is how the Children's Oncology Group functions.

Dr. Daghistani, *"To advance cancer treatment, we have to share our experience by forming large clinical trial groups so we can use the same state of the art treatment, and share the knowledge about the effectiveness of the treatment."*

To Learn More:
- Info on COGs Collaborative Research Model (https://childrensoncologygroup.org/index.php/childrens-oncology-group)
- COG Research Collaborations (https://childrensoncologygroup.org/index.php/research-collaborations)

Miami Cancer Institute's Involvement With COG

COG audits all cancer centers, and Miami Cancer Institute is a certified COG center. All Children's Oncology Group clinical trials are available at MCI.

To Learn More:
- Miami Cancer Institute (https://baptisthealth.net/en/health-services/cancer-services/pages/miami-cancer-institute.aspx)
- Childrens Oncology Group (https://childrensoncologygroup.org/)

MCI Trials

Part 4: Clinical Trials at Miami Cancer Institute

Trials Available Other Than Therapeutic

The Miami Cancer Institute offers a variety of clinical trials for our patients. They include clinical trials that provide Frontline therapy for different types of cancers, treatments that include Investigational medications, Biology trials to learn more about the different diseases, Survivorship trials, and Supportive Care trials.

To Learn More:

- NCI's Info on Types of Clinical Trials (http://www.cancer.gov/about-cancer/treatment/clinical-trials/what-are-trials/types)

(https://vimeo.com/175172959)

How Does the Medical Team Choose Clinical Trials?

The medical team selects clinical trials based on the common cancers seen in our community.

Clinical Trials for AYA Patients

The adolescent and young adult (AYA) cancer patient, as compared to the pediatric patient, can sometimes be caught in between. They sometimes need to be on adult clinical trials that are not part of the Children's Oncology Group (COG), or they're part of the COG as a subset of a larger pediatric opportunity. There is no one trial group for AYA patients, and it's unlikely that one will be created under the new NCI guidelines. Therefore, it's very important that any hospital taking care of AYA patients has access to both pediatric and adult trials to make sure that they bring the best clinical trials to the patient.

The Three Types of Phases of Clinical Trials

What is a Phase 1 Clinical Trial?

Phase 1 clinical trials usually involve a small number of patients with very advanced cancer that cannot be effectively treated with current standard therapies. The primary goals of Phase 1 studies are: to evaluate the safety of the new medication; to define the maximum tolerated dose that could be given to the patients without harmful side effects. A secondary goal of Phase 1 studies is to preliminarily define the potential anti-tumor effects of new medications.

What is a Phase 2 Clinical Trial?

Phase 2 trials usually follow Phase 1 trials. They test the effectiveness of the new drug on patients with a particular type of cancer, and also continue to monitor the safety of the new treatment.

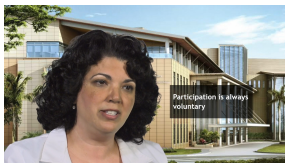
What is a Phase 3 Clinical Trial?

Phase 3 trials compare the new treatment to the current standard treatment for the specific type of cancer. If the new treatment turns out to be more effective, it usually becomes the standard for this particular type of cancer.

To Learn More:

- The 3 Phases of Clinical Trials (http://www.cancer.gov/about-cancer/treatment/clinical-trials/what-are-trials/phases)

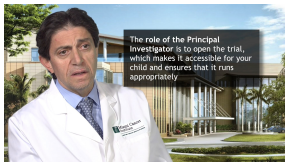
Not every child receives their therapy on a clinical trial at the Miami Cancer Institute. Only patients who consent to participate in a clinical trial receive their treatment as part of that clinical trial.



Our Team

Part 5: The Clinical Trials Team

The Role of the PI in Designing the Study



PI stands for Principal Investigator. The role of the Principal Investigator is to open the trial, which makes it accessible for your child and ensures that it runs appropriately. The majority of clinical trials come through the Children's Oncology Group, which has a head principle investigator for the entire country. However, every institution chooses a principle investigator for their hospital who makes sure that their trial at that hospital is carried out correctly.

Dr. Daghistani, *"I am the Principal Investigator of the Pediatric Oncology Department at the Miami Cancer Institute."*

Responsibilities of the Clinical Research Coordinator

(https://vimeo.com/175216851)

The Clinical Research Associate manages the pediatric clinical trials.

This includes...

- Completing regulatory requirements
- Distributing information to the healthcare team
- Providing the patient and their family with information about their treatment
- Working with Principal Investigator to pull protocol information such as eligibility requirements and roadmaps
- Maintaining patient files
- Submitting information to the Children's Oncology Group

The Role of the Institutional Review Board

The IRB, or Institutional Review Board, ensures the safety of participants in clinical trials by reviewing these trials for any safety issues. The IRB is a committee made up of medical professionals and members of the community to ensure that patients' rights are protected. They review these clinical trials at least yearly, and review the progress of these clinical trials to see if any issues or problems have occurred.

Process

Part 6: Steps in the Clinical Trials Process

The Protocol

A protocol is a document that contains all the information about the clinical trial. It includes the background information, the purpose of the study, the treatment plan, and the possible risks or benefits. Each protocol targets a certain patient population.

To be eligible for a trial means you meet the requirements for that specific study. This can include such things as:

- Specific diagnosis
- Extent of disease or staging
- Age at diagnosis

The Comprehensive Treatment Plan

The Comprehensive Treatment Plan or Roadmap, contains all of the therapy that you or your child will receive throughout the entire clinical trial. A roadmap can be altered once a clinical trial has started. It includes the patient's dosing schedule, their actual schedule, and any required observation that may need to be done by the entire team.

If the patient experiences any side effects, we will document that on the Roadmap and adjust the doses accordingly if the protocol allows for that. This way the entire team knows of any changes that were made.

(https://vimeo.com/175402050)

The Occurrence of an Adverse Event

An Adverse Event is an unwanted result of the treatment. Adverse Events are expected when patients receive treatments for cancer. Depending on the severity of the adverse event, the patient's treatment can be modified as specified by the protocol. They can be reported to the Cooperative Group and the Institutional Review Board. Patients who experience adverse events may or may not stay on the study, it depends on the severity of the adverse event and the specifications of the protocol.

The Research Coordinator is responsible for communicating regularly to the oncology team regarding the patient's status and any changes in the protocol or protocol requirements.

The Family Conference

The Family Conference is the most important step we take upon diagnosing a child with cancer. The Family Conference is the place where we inform the family and the patient of the name of their cancer, stage of their cancer, and the detailed treatment with the complication.

It's not only a medical team we have with the Family Conference. Our Pediatric Oncology support team includes social workers, psychologists, nurses and child life specialists. This team is created to help support the child and the family upon diagnosis to understand the details of the treatment, and the impact on the life of the child, and to be with this family during the whole journey of treatment and follow-up care.

Dr. Daghistani, *"The Family Conference is attended by anyone the family wants to bring with them. We encourage the parent/guardian to ask questions during the conference. From my experience, the problem with the parent/guardian is that they are in shock. A lot of the time, they really don't know what to ask. This is why I encourage the parent to bring a close relative and a close friend to help them ask the proper questions."*

What if We Have Questions After the Family Conference?

Dr. Daghistani, *"You will definitely have many questions after the Family Conference. My advice is that you educate yourself, formulate your questions, and come back and ask them. A lot of the time, families and patients feel shy because they don't want to bother their doctors. When you ask a question, you will benefit from it, along with your child. The more we communicate as a medical team, the more it benefits the family and patient."*

To Learn More:
- More Info on the Family Conference
(https://childrensoncologygroup.org/index.php/attending-the-informed-consent-conference)

The Consent Form is a document that helps the patient and the parents decide to participate in the clinical trial.

The Informed Consent Form explains what you should expect during the study...

- The Treatment Plan
- The medications given
- The risks
- The potenial benefits

Future

Part 7: Looking Towards the Future

Putting the Patient First

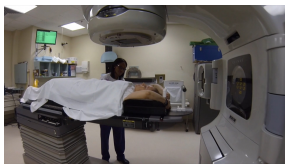
Dr. Mehta, *"At Miami Cancer Institute, we are leading research and treatment in pediatric cancer by putting the patient in the center of everything that we do. We believe that our approach of high tech and high-touch is the right way to take care of patients. We want to bring the best possible biology, clinical research, genomic medicine, and the highest technology that we can for the care of the patient. We want to deliver this in the most pleasant, most friendly environment for patients so that they can get the care that they have not received anywhere else in the world in terms of quality, and in terms of satisfaction. Miami Cancer Institute has several innovative and exciting projects. My two favorite projects are Proton Therapy and Genomic Medicine."*

Genomic Science

(https://vimeo.com/175402687)

The Genomic Project is designed to look at a patient's tumor and get an understanding of the genetic drivers behind the tumor. What makes it grow? What makes it progress? Can we find specific agents, specific drugs that can stop such a tumor from growing, by knowing what allows the tumor to grow? This is really cutting edge science.

Proton Therapy



Proton Therapy is cutting edge technology. What it allows us to do is to deliver the best possible form of radiation for our patients, to minimize side effects to the greatest possible extent. That means some very-difficult-to-treat tumors can now be treated with radiation, something that would not have been possible in the past.

Dr. Daghistani, "*Usually with standard radiation therapy, no matter how accurate you are while performing the treatment to only the cancerous tissue, you will always have what we call Scattered Radiation that will affect the new tissue that doesn't have the cancer. With Proton Therapy, you are 100% sure that the treatment is going only to the area of the cancer. This is why if we have a child who has a brain tumor, you only want Proton Therapy because you don't want your child to have secondary long-term side effects due to the treatment of the normal tissue, not the cancer."*