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Fast progress towards a cure

It's been almost two years since the inception of The Medulloblastoma Initiative (MBI). Not even in my wildest dreams did I imagine getting this far. **The MBI** is making great progress in its mission to find a cure for the most common malignant brain cancer affecting children.

The MBI now supports 13 laboratories that bring together some of the world's leading scientists. They work collaboratively and synergistically to find a cure for medulloblastoma as quickly as possible. Among our achievements is the citation of The MBI in Nature (the most important scientific journal on the planet) as a supporter of an incredible discovery regarding the origin of medulloblastoma. And, of course, there is a historical milestone — the development of the first line of human stem cells capable of modeling group 4 medulloblastoma in laboratory animals. This achievement has opened the path to enable the start of clinical trials in patients in the coming months.

It is always important to keep in mind that none of this would have happened without the tireless and steady leadership of Dr. Roger J. Packer, creator of this beautiful project. Dr. Packer is a world reference in pediatric brain tumor research and has done a tremendous job in coordinating this great team of laboratories and scientists.

Another point worth highlighting is the **fruitful partnership established** between MBI and the Children's National Hospital Foundation in Washington, D.C. Through the joint work of both teams, we have begun a really important effort to disseminate our project. This will serve not only to raise funds in the U.S., but also to increase societal awareness of the lack of public policies to encourage investment in oncological research for children.

Finally, I would like to thank all the donors, researchers, collaborators, and friends around the world who, in one way or another, are contributing to changing the history of pediatric brain cancer.

Thank you very much!



A reason to believe. A reason to exist.

The Medulloblastoma Initiative (MBI) is the result of a lived experience — or more than that, of a life-changing experience. A first-person experience that sparked action that has already begun to transform thousands of lives.

Cancer is a complex theme. Facing it requires addressing many needs and establishing numerous task forces. It is necessary to sensitize people and raise awareness. It is necessary to provide support to patients and their families. It is necessary to create mechanisms for specialized care. It is necessary to build clinical infrastructure to treat patients, and also to ensure access to it.

And it is necessary to enable research. Because only research will find a cure.

We at MBI work alongside several other public and private institutions with which we share this steadfast passion — each with a focus. Our focus is research.

Our objective is ambitious and urgent. And because of that, our mission must be clear. And clear it is: we exist to raise funds to enable scientific research of the highest level in the search for a cure for medulloblastoma.

The Medulloblastoma Initiative. All children deserve a future.



Mauro Dorfman
Executive Coordinator, The Medulloblastoma Initiative

in www.linkedin.com/in/cian/





MBI News

The Cure Group 4 Consortium — which is supported by The Medulloblastoma Initiative (MBI) — has scheduled its next Research Workshop for **22 May 2023**. Every year, the meeting brings together researchers and physicians seeking new treatment approaches for the most common malignant brain tumor in children, medulloblastoma, and especially subtype 4.

In 2022, the group held its <u>first Research Workshop</u> at the Children's National Research & Innovation Campus, in Washington, D.C. Consortium members discussed research priorities, including immunotherapy, molecular-based therapy, and a combination of these modalities as an initial treatment protocol. Next steps and timelines were also covered.

A passion for life

In May 2023, MBI founder Fernando Goldsztein will join the Children's National Hospital Foundation Board. Children's National, an MBI supporter since inception, believed in our vision of seeking funding from private donors to invest in research and embraced the project. The partnership grew and, among other important collaborations, Goldsztein was invited to join the Foundation Board.

Members of all Children's National Boards must be leaders in their communities. Qualifications expected of candidates include diplomacy, a natural ability to nurture relationships and to facilitate and build consensus between different parties; integrity, credibility, and a passion for improving the lives of children and their families.



First Cure Group 4 Consortium Research Meeting, held at the Children's National Research & Innovation Campus, in Washington, D.C.



An important part of our work at MBI is reaching out to people to tell a story: <u>How did MBI begin?</u> Why does the idea of supporting research with private donations make sense? How does this effort complement other approaches to stop cancer? In the last year, many people listened and spread the message in important spaces.





Daniel Scola, a journalist working with the largest communication network in southern Brazil (RBS), received a diagnosis of medulloblastoma in 2021. Although this type of cancer usually affects children, it sometimes appears in adults. Scola identified with the MBI story because he believes he was saved "thanks to science, good professionals, and a good hospital"—as he himself wrote in his GZH column.



The Brazil Journal, which focuses on economics and business, <u>published</u> the MBI story in its philanthropy section. Reporter Giuliano Guandalini explains: as a relatively rare tumor, medulloblastoma is not among the research priorities of funding agencies [as is the case with other types of cancer in children]. Even though it seemed like a wild dream, Fernando Goldsztein left Porto Alegre, a city in the South of Brazil, taking MBI to the best positioned international laboratories to work on the cure of medulloblastoma. And, if anyone thought that the funds raised would not be enough to advance the research — an expensive activity, MBI proved the opposite: in less time than expected, the volume raised made a difference, and more and more people are willing to donate.



Fernando Goldsztein's account of the MBI was published in the MIT Sloan alumni website. His year at MIT Sloan (the business school at the prestigious Massachusetts Institute of Technology) was enlightening, and certainly helped him face a huge challenge—finding ways to help his own son overcome medulloblastoma. This is when he first thought about creating the MBI. By making this idea a reality, bridging the gap between donors and scientists, the possibility of helping thousands of children became an additional force driving the project forward. Not by chance, MBI's story was one of the top 10 MIT Sloan alumni stories in 2022.





A brief history



---- June 2021

The Medulloblastoma Initiative (MBI) is established with support from Dr. Roger J. Packer, from the Children's National Hospital in Washington, D.C, USA.



The Cure Group 4 Consortium is established to unravel the molecular and immunological bases of this type of pediatric cancer. The consortium is driven by a clear goal: to accelerate the development of a cure protocol that will save the lives of thousands of children around the world. In addition to Dr. Roger J. Packer, principal investigator, the original Consortium group included Drs. Eugene Hwang, Brian Rood, Conrad Cruz, Yanxin Pei, Michael D. Taylor, Vijay Ramaswamy, Robert Wechsler-Reya, and Duane A. Mitchell









September 2021 ····

Dr. Sheila Singh joins the Cure Group 4 Consortium.

The first million

The first million dollars from non-founders is raised, following dissemination of the MBI.



EMORY

---- December 2021

Dr. Tobey McDonald joins the Cure Group 4 Consortium.

January 2022 ...

Dr. Sheila Singh makes an important discovery, establishing the first line of human stem cells capable of generating Group 4 medulloblastoma in a laboratory model — a great step towards a cure.

---- March 2022

The <u>MBI website</u> is launched. Dr. Javad Nazarian joins the Cure Group 4 Consortium.





April 2022 ··

The first MBI Report is launched — at that point, MBI had already secured US\$ 6.1 million for medulloblastoma research. Drs. Lena M. Kutscher and Carl Koschmann join the Cure Group 4 Consortium.

···· May 2022

First Cure Group 4 Consortium Research Workshop.

September 2022 ·

Three Consortium researchers — Robert J. Wechsler-Reya, Michael Taylor, and Vijay Ramaswamy — contribute to a groundbreaking finding about the origin of medulloblastoma and co-author a paper published in Nature, one of the most important scientific journals in the world.

October 2022

···· November 2022

Dr. Dalia Haydar joins the Cure Group 4 Consortium.

Children's Nation

Children's National produces and launches No Time to Lose, a video narrated by Fernando Goldsztein, sealing the partnership with MBI.

January 2023

Children's National produces an Impact Report describing the work done by the MBI, further strengthening the partnership between the two organizations.





A happy handshake

The year 2022 will no doubt be remembered in MBI history for the consolidation of an executive partnership with the Children's National Hospital. A center of excellence in healthcare and research, Children's National was an early MBI supporter, and was able to apprehend the transformative potential of MBI for medulloblastoma research.

The handshake between the two organizations came through actions such as the production of the video **No Time to Lose**. In addition, Children's National dedicated a beautiful publication to MBI in the form of an Impact Report—which MBI is proud to reproduce below.

The Impact Report reflects a strategic partnership and opportunities for collaborative creation to which each partner contributes their best—a powerful recipe for success. As stated by Drs. Singh and Haydar: bringing together people who see things from different perspectives allows a more comprehensive approach to making a treatment work; and, if there is a group capable of finding a cure, it is undoubtedly the Cure Group 4 Consortium.

The Impact Report is also a direct gesture of appreciation to our donors. The concept of science that advances by blocks that support each other is well known. Each discovery is built on layers of previously produced knowledge, which serves as the basis for new ideas.

MBI's goal is to add a cornerstone to the building: donors, partners who listen to science and have a clear vision of the children and families that await along this path. They are the ones making MBI's bold idea a reality, and redefining global medulloblastoma research so we can find a cure.

Enjoy!



The Medulloblastoma Initiative

Impact Report | January 2023

Every day counts for children with deadly brain tumors. Parents and loved ones ask: Can we step closer to cures? Can we increase the pace of progress? Can we leap for breakthroughs that save lives?

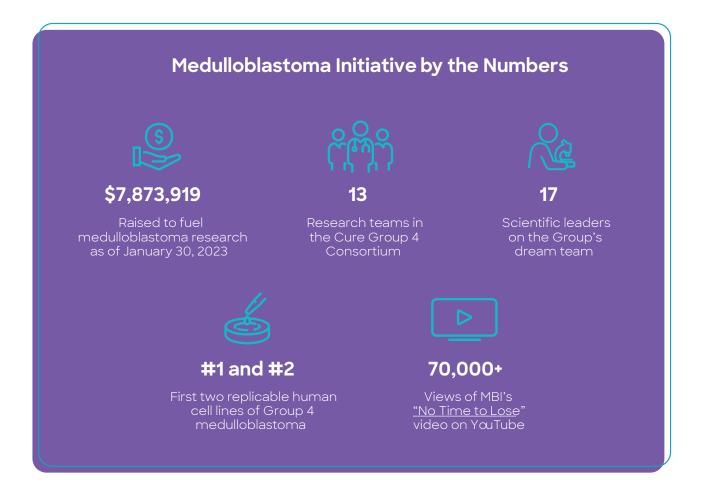
<u>The Medulloblastoma Initiative (MBI)</u> answers yes. Together, we can and we will. There is no time to lose for the young people we love. Philanthropy will make a difference for thousands of children every year.



MBI donors join a global movement that is redefining research into medulloblastoma, the most common form of pediatric malignant brain tumor. The need for new therapies is particularly urgent for patients whose cancer relapses. We currently lose almost all of them.

Your generosity fuels unprecedented global scientific collaboration through the MBI's top priority – the Cure Group 4 Consortium. This pioneering global network of investigators – assembled by Roger J. Packer, M.D., who directs the Brain Tumor Institute at Children's National Hospital in Washington, D.C. – is yielding new hope for patients, particularly those with relapsed Group 4 medulloblastoma. MBI partners with Children's National to direct 100% of every donation to research.

Thank you for joining MBI in our urgent mission. We present this report on your philanthropic impact in 2022 with deep appreciation.



A Year of Progress - Building Blocks for Breakthroughs

The Consortium gained significant momentum in 2022. Support from MBI helped Consortium scientists achieve key milestones in our journey to cures.

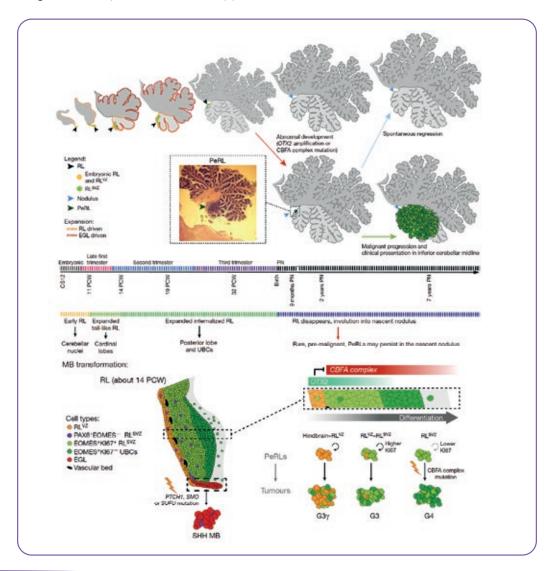


"We are seeing real growth, which has the potential to yield tangible results rapidly. This collaboration is changing the game when it comes to Group 4 research."

- Roger J. Packer, M.D., Director, Brain Tumor Institute, Children's National Hospital; Principal Investigator, Cure Group 4 Consortium

The following achievements highlight the transformational power of MBI investments in research:

The origin of medulloblastoma — Three Consortium members contributed to the groundbreaking discovery of how medulloblastoma develops in pregnancy and childhood. The study, published by the prestigious journal Nature in September, traces the origins of medulloblastoma to mutations of a cell type found only in the developing brains of children. The paper focused on Group 4 tumors specifically. These blockbuster results raise the possibility that we can detect and treat medulloblastomas before they ever pose a threat. "Preventing cancer from happening in the first place instead of treating it after it happens is the best possible outcome for children," says Consortium member Michael Taylor, M.D., Ph.D. — then of the Hospital for Sick Children (SickKids) in Toronto and now at Texas Children's Hospital — who helped lead the study. Consortium members Vijay Ramaswamy, M.D., Ph.D., of SickKids, and Robert Wechsler–Reya, Ph.D., formerly of Sanford Burnham Prebys Medical Discovery Institute and now of Columbia University, also contributed to the landmark findings thanks in part to the MBI's support.



• The first two human cell models of Group 4
medulloblastoma — Sheila Singh, M.D., Ph.D., of
McMaster University in Ontario, achieved a historic
feat in 2022. Her lab team produced the first
two replicable human stem cell lines capable of
generating Group 4 medulloblastoma tumors
in mice. Having a human cell and animal model
of the disease opens the door to clinical trials for
drugs to treat Group 4 within one to two years. Cell
lines from the Singh lab are now available to every
researcher within the Consortium. (Please see the
feature on page 6 for more on Dr. Singh and this
transformational development.)



- Multiple mouse models to speed the arrival of clinical trials The Consortium accelerates progress by building synergies between the world's leading experts. Developing reliable animal models for Group 4 medulloblastoma is a key part of the pipeline to facilitate clinical trials of new drugs.

 Dr. Wechsler-Reya is leading this effort in collaboration with a global team. Members include:
 - -Lena M. Kutscher, Ph.D., of Heidelberg University in Germany
 - -Tobey MacDonald, M.D., of Emory University School of Medicine in Atlanta
 - -Carl Koschmann, M.D., of the University of Michigan

The team identified six Group 4 mouse models in 2022. Dr. Koschmann's lab is studying these models to identify which ones deliver drugs most effectively into the brain. Having these models in place will speed drug development when the Consortium develops a potential breakthrough therapy.

- Candidates for cures Drs. MacDonald, Singh, Wechsler-Reya and Koschmann are collaborating to determine which drugs show the greatest promise to help children survive relapsed Group 4 medulloblastoma. To date the following combination therapies show the highest likelihood of success:
 - -A BMI1 inhibitor drug in synergy with other agents
 - -ONC206 in combination with other drugs

The development of the first human Group 4 cell line in Dr. Singh's lab is supercharging these efforts. For the first time, the team has the opportunity to test drugs on Group 4 tumors. Signs of efficacy in these models will provide the basis for drug trials in patients. The Consortium is aiming to launch such a trial in 2023.

• Pioneering immunotherapy to destroy deadly tumors — harnessing the body's own disease-fighting powers represents an emerging frontier in oncology. The Consortium is poised to make rapid progress by combining the expertise of Duane Mitchell, M.D., Ph.D., of the University of Florida and Dalia Haydar, Pharm.D., Ph.D., of Children's National, the newest member of the Group 4 team. Dr. Mitchell is pursuing a novel approach that may enable T-Cells to single-out and attack whole medulloblastoma tumors. Dr. Haydar recently came to Children's National from St. Jude's Children's Research Hospital, an institution with deep expertise in creating chimeric antigen receptor cells (CAR T-cells) designed to seek and destroy cancer cells. She continues to collaborate with St. Jude's to develop CAR T-cells specific to Group 4 medulloblastoma. (Please see the feature on page 7 for more on Dr. Haydar and her work to create a "living drug" to fight medulloblastoma.)



So Much to Offer: Leah's Story

Leah, 10, loves many things. She loves dancing, the school library, her teachers (she gets perfect grades even when she misses lots of school) and reading Harry Potter. She loves to learn and she is good at it. This helps her as a patient with relapsed Group 4 medulloblastoma.

In addition to learning about what she calls "the medical stuff," Leah figured out something even more important. "I can get through anything if I believe in myself," she says.

Elena and Neal, Leah's parents, agree and are doing everything they can to make sure that happens. That includes their embrace of the MBI community as donors and fundraisers. "Leah has so much to offer in the future," says Elena.

In 2022, Elena and Neal came across MBI while doing research about Leah's condition. "There hasn't been enough focus on Group 4 in research," Elena says. "I was excited when I learned about MBI and its founder, Fernando Goldzstein," she says. "His family is in a similar situation as ours. His focus on what's possible through research lines up with our focus."

Elena and Neal began supporting MBI philanthropically and encouraging family and friends to join them. Their goal is to raise at least \$50,000 for the Cure Group 4 Consortium. They appreciate the way in which the Consortium is speeding progress by approaching the task of discovering cures from many possible approaches simultaneously.

In addition to envisioning a brighter future, Leah's family – which includes her older brother Jack – loves to make music together. Elena and Neal play in a Boston indie rock band called Polyethylene. Back home, they join Leah and Jack on instruments. In the "family band," Leah plays the piano

or drums, Neal plays guitar, Jack plays cello or keyboards, and Elena can be found on bass, saxophone, flute or vocals. "We kind of just make up stuff when we play together," Neal says. "I love seeing Leah do all the things she loves to do," Elena says.



Rather than setting up a FB fundraising page, or a Go Fund Me, I'm asking donors to donate directly on the organization's page, to avoid scams and service fees, so that all funding goes directly to the cause. If you donate, please list your donation as "in Honor of Leah", so that the organization can track our donations and I can provide updates on the progress toward my goal, which is \$50,000.

request along to others.



No Time to Lose

In 2022, MBI collaborated with Children's National to create No Time to Lose, a video to raise awareness about the urgency of finding cures. The video features MBI founder Fernando Goldsztein and Dr. Roger J. Packer of Children's National. In it, Goldsztein shares the story of his son Frederico, who has relapsed Group 4 medulloblastoma. We hope that every member of our community will share this video with their networks to spread the word. As Goldsztein quotes from the Talmud in No Time to Lose, "whoever saves one life saves the world entire."



Dr. Sheila Singh is one of Canada's foremost pediatric neurosurgeons and directs the Centre for Discovery in Cancer Research at McMaster University in Ontario. A specialist in stem cell biology, Dr. Singh is renowned as the first scientist to isolate an abnormal stem cell – the brain tumor initiating cell (BTIC) – in the central nervous system. These cells are associated with 12 different types of brain tumors, including pediatric medulloblastoma. This landmark finding now informs multiple investigations into the origins of brain tumors within her 24-member laboratory. A novel hypothesis drives this work: the observation that pediatric brain tumors may first arise during the brain's developmental stage.

Her team creates stem cell lines that seek to replicate this early development, which creates the ideal test best for finding cures. She was thrilled to learn about the Consortium, which she joined in 2021. She quickly became a lynchpin of the dream team's progress.

Dr. Singh performed brain surgeries on two Group 4 tumor patients in late 2021 and early 2022. She asked her team to isolate the stem cells and attempt to replicate them. Remarkably, it worked. Her lab had created the first replicable human stem cell lines capable of generating Group 4 medulloblastoma tumors. The news got better: these two cell lines both proved capable of generating Group 4 tumors in mice. This will enable her and fellow investigators across the Consortium to test the efficacy of drugs such as BMI1 inhibitors. This drug is a good candidate since it targets that gene that controls cancer stem cells in medulloblastoma.

She credits this crucial discovery to MBI. "The Consortium has positioned us very well for success," she says. "finally we have cells that have grown in a lab dish that also have developed tumors in mice."

The Consortium's collaborative nature compounds the speed and likelihood of progress for children with relapsed cancer. "All of our research informs each other," she says. "You know you are on the right track when our findings agree." The 2022 paper in Nature – co-authored by Drs. Taylor, Ramaswamy and Wechsler-Reya – on the origin of medulloblastoma exemplifies this. It supports Dr. Singh's hypothesis about how medulloblastoma arises in the brain's early development – likely linked to an abnormal stem cell. "It's very gratifying to me," she says. "If this problem is going to be solved, it's going to be solved by this group. I'm filled with gratitude for Mr. Goldsztein and the MBI for enabling the science."

A Living Drug to Cure Cancer

Dalia Haydar, Pharm.D., Ph.D., is the newest member of the Consortium. She joined our dream team when she arrived at Children's National in October 2022. She brings important expertise in developing CAR T-cells that harness the

destroy tumor cells. She developed this expertise at St. Jude's Children's Research Hospital. She continues to work closely with Drs. Stephen Gottschalk and Martine Roussel – leaders in the fields of adoptive immunotherapies and medulloblastoma – at St. Jude's.

body's own immune system to seek and

Dr. Haydar welcomes the challenge of working on a potential immunotherapy for Group 4 medulloblastoma. "I'm particularly interested in this tumor because it poses so many research challenges and it's so aggressive," she says. "I am very intrigued by those challenges, and they keep me awake at night. Being able to investigate this very unique subtype of brain tumors and being able to apply my expertise and use the support from different resources excites me a lot."

She calls immunotherapy a "living drug," since the CAR-T cells can multiply within the body and eradicate tumors naturally. This raises the possibility that we can not only cure medulloblastoma, but also avoid lifelong cognitive and physical side-effects from surgery and radiation. Another advantage of immunotherapy is that it uses a patient's own cells, which makes therapies more precisely tailored to each patient's unique biology. The approach has already shown remarkable success in patients with leukemia. The Consortium enables Dr. Haydar to work alongside Yanxin Pei, Ph.D., one of the world's top medulloblastoma experts, to develop mouse models to test immunotherapies. They are working to achieve a CAR-T breakthrough within the next 18 months.

"We can come together and bring breakthroughs faster to patients," Dr. Haydar says about her collaborations across the Consortium. "Bringing all of the investigators together – people who see things from different angles – enhances our focus on how we make a therapy work. You don't find this in a different place. The Consortium brings all of our strength together."

The Dream Team – Members of the Cure Group 4 Consortium

Roger J. Packer, M.D. , Children's National Hospital, Washington, D.C.

Eugene Hwang, M.D. , Children's National Hospital

Robert Wechsler-Reya, Ph.D., Columbia University, New York

Duane Mitchell, M.D., Ph.D., University of Florida

Michael Taylor, M.D., Ph.D., Texas Children's Hospital

Vijay Ramaswamy, M.D., Ph.D., SickKids, Toronto, Canada

Yanxin Pei, Ph.D, Children's National Hospital

Brian Rood, M.D, Children's National Hospital

Conrad Cruz, M.D., Ph.D., Children's National Hospital

Sheila Singh, M.D., Ph.D., McMaster University, Ontario, Canada

Tobey MacDonald, M.D., Emory University School of Medicine, Atlanta

Lena M. Kutscher, Ph.D., Heidelberg University, Germany

Stefan Pfister, M.D., Heidelberg University, Germany

Dalia Haydar, Pharm.D., Ph.D, Children's National Hospital

Javad Nazarian, Ph.D., Children's National Hospital
Carl Koschmann, M.D., University of Michigan
Craig Daniels, Ph.D., SickKids



Progress in Sight

The Consortium continues to make progress in an array of additional areas. We look forward to sharing achievements on other crucial initiatives in the months to come. These include:

- Dr. Nazarian's **development of liquid biopsy** to monitor how a child's medulloblastoma is responding to treatment, detect tumor growth and provide an earlier indicator of recurrence
- Dr. Rood's use of **state-of-the-art technologies**, including proteomics, to investigate the molecular signature of Group 4 tumors work that will accelerate with the arrival of the Group 4 cell lines from Dr. Singh's lab
- The rapid development of new minimally invasive neurosurgical approaches that promise to complement therapies developed by the Consortium; these include stunning developments in the field of focused ultrasound technology that are offering new hope to brain tumor patients worldwide

The Difference You Make

Every year, thousands of children around the world learn they have medulloblastoma. Too many of them still die from their cancers. Historically, the condition's rarity among all children prevented it from receiving sustained, focused and coordinated attention from medical science. The Medulloblastoma Initiative has changed this pattern forever. Its philanthropy is a catalyst for global collaboration with an unprecedented focus on hard-to-treat and relapsed Group 4 tumors.

Together, we are speeding the arrival of cures and treatments that improve health over entire lifetimes. Thank you for your role as a member of this movement.

The Medulloblastoma Initiative

The Medulloblastoma Initiative (MBI) is pursuing a bold vision to eradicate medulloblastoma – the most common malignant pediatric brain tumor. This will save the lives of thousands of children worldwide every year. MBI raises funds to fuel its most urgent priority – discovering treatments for relapsed Group 4 medulloblastoma, a deadly condition that lacks treatment options. 100% of all donations to MBI support research.

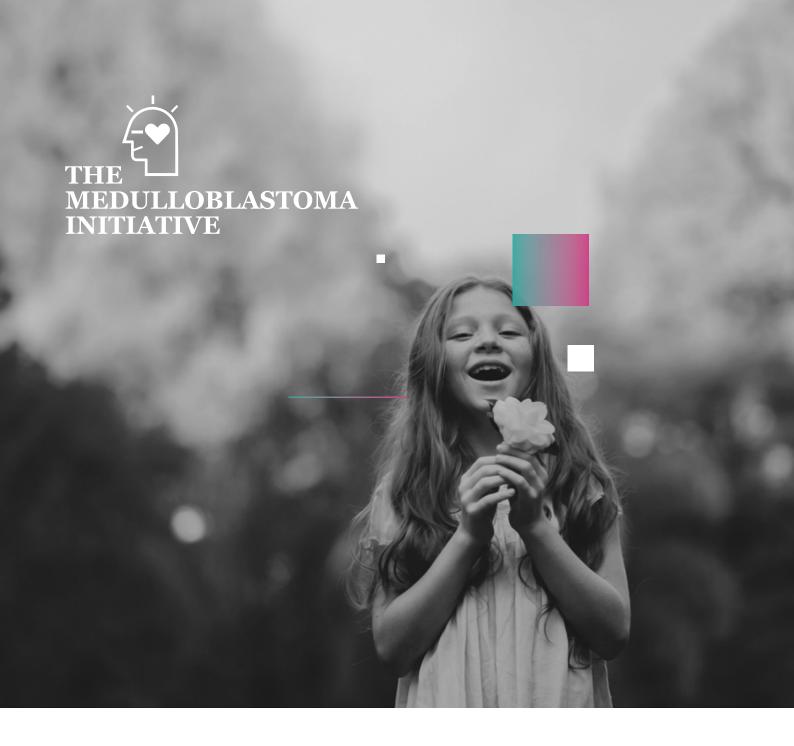


In 2021, MBI established the Cure Group Four Consortium with the guidance of principal investigator Roger J. Packer, M.D., of Children's National Hospital in Washington, D.C. This pioneering research network links 13 laboratory teams in the United States, Canada, and Germany, Rather than working in silos, these teams work together synergistically to accelerate progress.

The Cure Group Four Consortium aims to develop a new therapeutic treatment and a standard protocol of care for Group 4 medulloblastoma within 18 to 24 months – faster than the traditional three-to-five-year timeline. With children's lives at stake, there's no time to lose.



ChildrensNational.org/Giving



Just say yes!

"Every day counts for children with deadly brain tumors. Parents and loved ones ask: Can we step closer to cures? Can we increase the pace of progress? Can we leap for breakthroughs that save lives?"

MBI answers yes. Together we will get there. Philanthropy will make the difference for thousands of children, every year.

Join us in finding a cure for medulloblastoma.

<u>Give now — our children cannot wait.</u>

Give it a thought

phi·lan·thro·py $noun \setminus fa$ -lan(t)-thra- $p\bar{e}$

Goodwill toward one's fellow human beings especially as expressed through active efforts to promote human welfare; an act or instance of deliberative generosity.

How can you contribute?

- Spread the word about the project on social media.
- Learn the project facts and endorse it.
- Share this information with people who can contribute.
- Consider what you can do for the project as a volunteer.
- Give money.

Just say yes!





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Every child deserves a future.
www.mbinitiative.org