PRESS RELEASE

Medela's in-house clinical trials help usher in a new generation of devices that benefit millions of moms around the world

Baar, 8 May 2017. Why have in-house clinical trials? They bring mothers and Medela scientists together directly. Mothers talk, and the scientists listen, gaining profound new insights into what mothers and babies still need to truly thrive along the breastfeeding journey. Those insights are translated into design improvements and benefits for "Medela Moms" in over 100 countries. That is why Medela established its Clinical Affairs unit.

UNICEF states: "Breastfeeding is a miracle investment… the closest thing the world has to a magic bullet for child survival." [i] Every year, new scientific evidence reinforces the fact: Nothing compares to the value of breast milk and breastfeeding in the first days, weeks, and months of an infant's life. For 130 million babies born around the world every year, breast milk offers unparalleled fuel for the brain, the organs, and the immune system; in other words, it sets babies on a lifelong path of better health. That is why, since its inception in 1961, Medela has been devoted to supporting mothers and babies along the breastfeeding journey.

Deep scientific research and rigorous clinical studies have provided the foundation and impetus for Medela's continuous pioneering in this field. Medela's unrestricted research grants have funded numerous breakthroughs which have dramatically advanced the relatively new field of breastfeeding and breast milk science. In fact, in 2005, Medela's funding enabled the University of Western Australia to expose the error in a 160-year-old model of the lactating breast and reveal the true anatomy of the lactating breast for the first time[ii].

"Although we have seen terrific scientific breakthroughs in recent years, there is still so much to be discovered about how moms breastfeed, and how we can help each and every mom and baby to derive the greatest benefits from it," says Dr. Danielle Prime, senior research scientist and part of Medela's Medical Research unit.

"Clinical trials allow us to test concepts that come from basic research. It's an important step in delivering on our promise to bring research to life to

support moms and babies." says Prime. "Clinical trials confirm, for example, the basic research conclusion that there is a vast spectrum of breast shapes, and that we can refine our designs to be more effective, efficient, and comfortable for a greater variety of moms."

"That is why we established the Global Clinical Affairs unit: to apply our cumulative knowledge and learn directly from moms, through safe and ethical in-house clinical trials," says biologist and immunologist Dr. Lennart Ivarsson, head of the unit, with over a decade of clinical study expertise in medical technology.

All Medela clinical trials adhere to the highest independent standard for Good Clinical Practice (ISO 14155) set by the supranational International Organisation for Standardization (ISO). Also certified by all national ethical and medical authorities in countries where in-house clinical trials are conducted (Swissmedic in Switzerland, the FDA in the USA, etc.) Global Clinical Affairs provides a forum for working directly with mothers to test new approaches and products. All clinicians are certified, sites are selected according to official criteria, and participants are informed thoroughly before they give their consent to participate.

Ivarsson says, "The test of an innovation is whether it fulfils a need never met before. Does this new design fill a gap between the state of the art and individual breastfeeding needs? Does it still need work? For certain studies, instead of relying solely on second-hand feedback from external hospitals and clinics, we can hear from moms in their own words what works, and what kind of support they still need, so we can create that for them."

How is safety assured in a clinical trial? Ivarsson says, "We follow the most robust laws and guidelines set by the ISO and national health authorities, meticulously conducting and monitoring the studies, and reporting on any "adverse event". Even the best research and calculations sometimes come up short when a design is tested in real life. Clinical insights are the clearest way to validate functionality, compare features, and select only the best designs to offer moms in the market."

Although in-house clinical trials have been optional to date, the new EU Medical Device Regulation (MDR), due to take effect this month, will make such competence centres obligatory for all medical device producers.

Stephen Flint, Chief Technology Officer at Medela, says: “As a research- and evidence-based firm, we have always maintained a staff of highly trained scientists. Before any kind of regulation required in-house clinical trials, we realized that getting feedback directly from moms could raise the user-centricity of breastfeeding support devices to a new level. We got certified and got to work. And now we are ushering in a new generation of devices that benefit millions of moms around the world.”

About Medela:
Founded in 1961 by Olle Larsson and headquartered in Switzerland, Medela today is led by his son Michael Larsson. Medela concentrates on two business units: "Human Milk", global leader in the development and production of breast milk feeding products and solutions, and "Healthcare", which engineers and manufactures highly innovative medical vacuum technology solutions. Medela conducts basic research in partnership with leading scientists, medical professionals and universities, and uses the research results in the development of its breastfeeding products and solutions. Medela has 18 subsidiaries in Europe, North America and Asia, and together with independent partners distributes its products in more than 100 countries.

Medela Press Contact:
Olivia Coker-Decker
Corporate Communications Specialist
Medela AG
Lättichstrasse 4b
6340 Baar, Switzerland
Email: olivia.coker-decker@medela.ch
Phone: +41 41 562 13 67
Mobile: +41 79 109 94 69

[i] https://www.unicef.org/nutrition/index_breastfeeding.html
[ii] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1571528/