

Subject: [EXT] statement of support for CLIN220316

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From: Jennifer Hoskovec

To: Lana Morales

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Below is a written comment submission for the September 24 ICOC.ARS Meeting re: CLIN220316: In Utero Stem Cell Transplantation to Prevent Bone Marrow Failure and Cancer in Fanconi Anemia

BillionToOne is a California-based molecular diagnostics company. We have no financial, scientific, or contractual relationship with this program and no role in its enrollment; our tests are screening tests, not diagnostic tests, and we do not have any expertise on the merits of the proposed therapeutic approach. We write only to address one point in the review: the size of the population that could realistically be identified prenatally and in time. We offer a maternal carrier screen with reflex single-gene non-invasive prenatal test that assesses fetal risk directly from a maternal blood draw, rather than inferring it from sequential parental carrier testing, and we recently expanded that menu to include Fanconi anemia complementation group C. In our experience with other recessive conditions added to our panel, making direct fetal risk assessment available has increased the number of pregnancies identified as high-risk during gestation rather than after delivery, because it removes the step at which identification most often fails: partner testing. We would also note that we operate nationally, not only in California, and test hundreds of thousands of pregnant patients every year. Families who learn of their elevated risk through our screening test and then obtain a diagnosis elsewhere in the country may seek out a California trial, as families facing ultra-rare diagnoses routinely travel for access. For both reasons, we would respectfully suggest that the eligible population is not fixed at historical California incidence, and is more likely to grow over the award period than to remain static.

Thank you,
BillionToOne Clinical Team

Jennifer M. Hoskovec, MS, CGC

VP Medical Affairs, Prenatal

C : (713)443-1589

E : jhoskovec@billiontoone.com

i **UNITY** by **BILLIONTOONE** **X** **in**

T : (833) 408-1488 **F** : (833) 915-0146

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