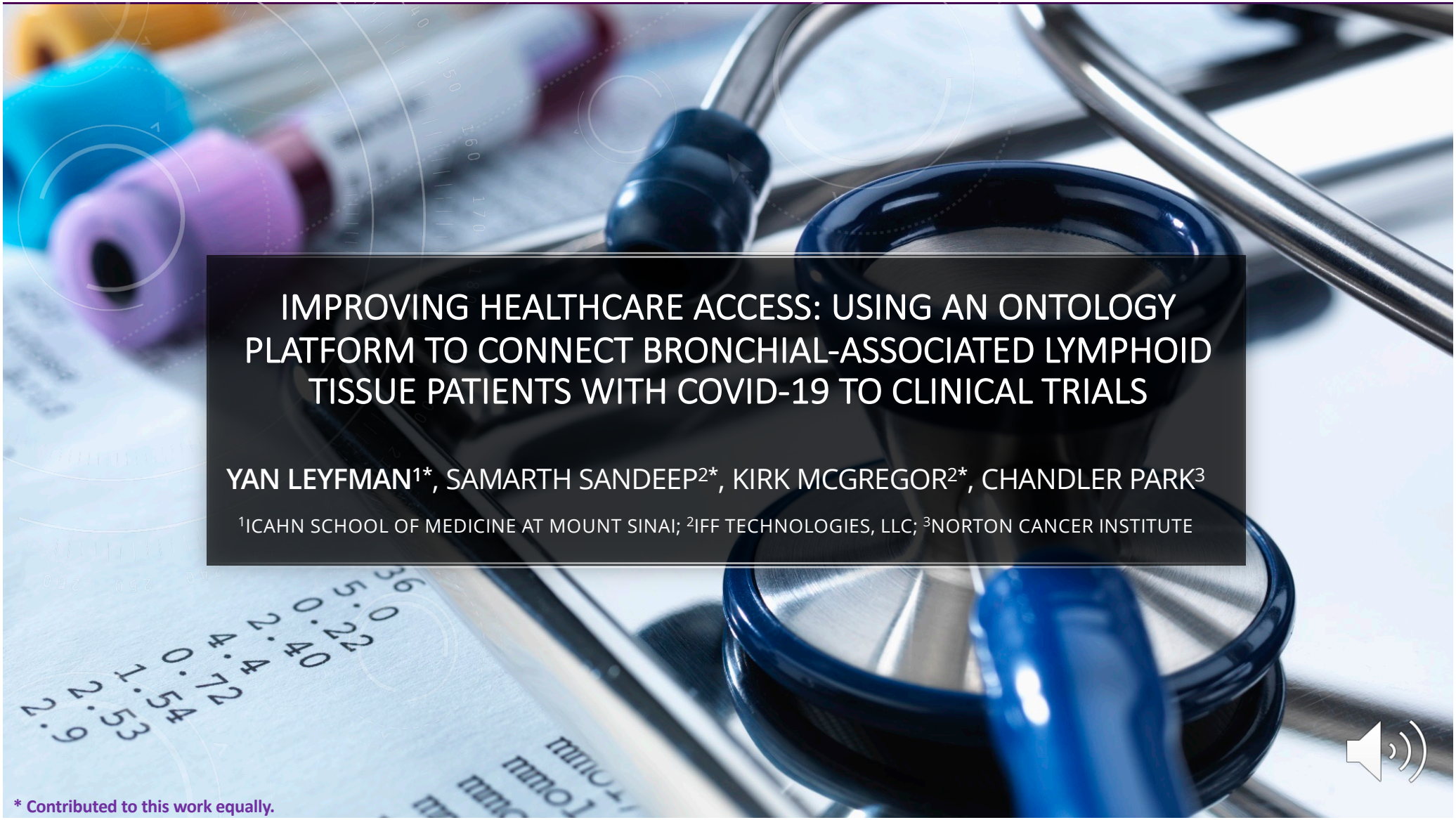

IMPROVING HEALTHCARE ACCESS: USING AN ONTOLOGY PLATFORM TO CONNECT BRONCHIAL-ASSOCIATED LYMPHOID TISSUE PATIENTS WITH COVID-19 TO CLINICAL TRIALS

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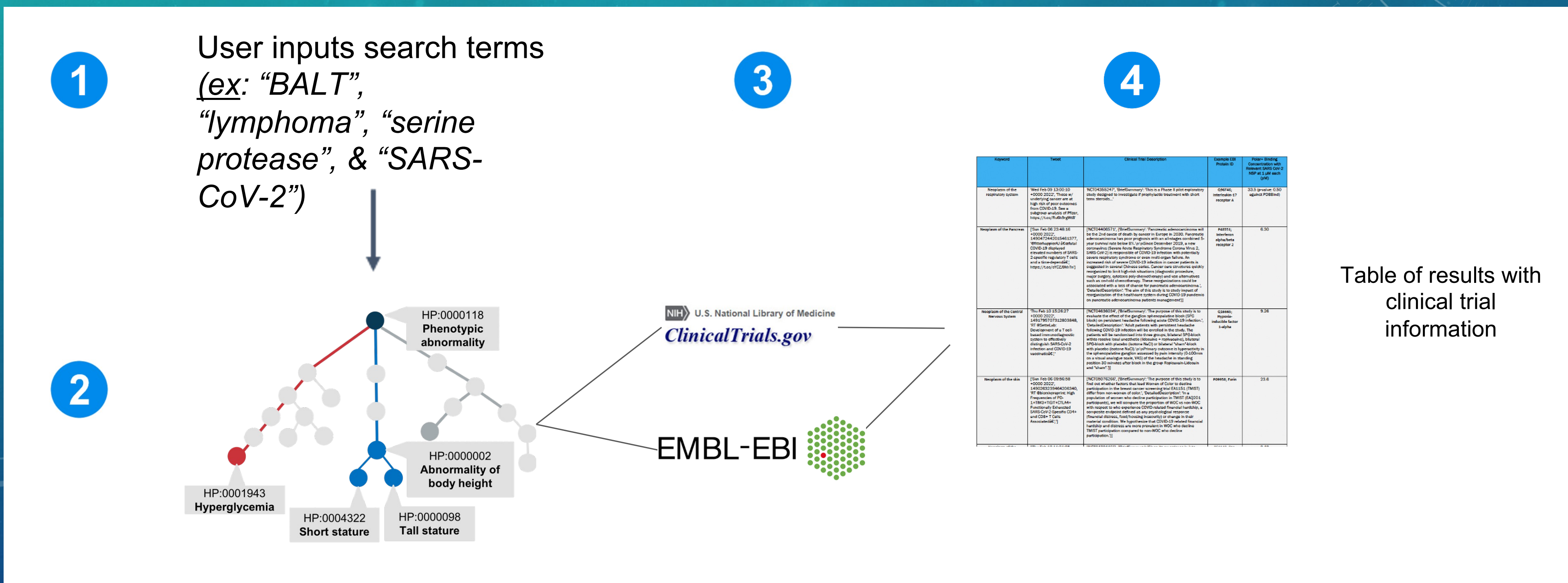
STUDY AIM

To use a computational approach to identify connect BALT patients afflicted with COVID-19 to clinical trials to overcome access limitations.

METHODS



RESULTS

PubMed Abstract	EBI Accession Code	ClincialTrials.gov Summary
We used the dataset of the SWIFT-DIRECT trial, which randomized 408 patients to IVT+MT or MT alone. Potential interactions between assignment to IVT+MT and expected time from onset-to-needle (OTN) as well as expected time from door-to-needle (DTN) were included in regression models. The primary outcome was functional independence (modified Rankin Scale (mRS) 0-2) at 3 months. Secondary outcomes included mRS shift, mortality, recanalization rates, and (symptomatic) intracranial hemorrhage at 24 hours.	Q16553: Lymphocyte Antigen 6E	Immunotherapy based on Adoptive Cellular Transfer (ACT) uses several types of immune cells, including dendritic cells, cytotoxic T lymphocytes, lymphokine-activated killer cells, and NK cells. NK cell-based immunotherapies are an attractive approach for treating diseases because of their characteristic recognition and killing mechanisms; they are involved in the early defense against infectious pathogens and against MHC class-I-negative or -low-expressing targets without the requirement for prior immune sensitization of the host and are able to lyse target through the release of perforin and granzymes and using antibody-dependent cellular cytotoxicity pathways mediated by Fc receptor for IgG (CD16). The aim of this project is to evaluate the safety and immunogenicity of allogeneic NK cells from peripheral blood mononuclear cells (PBMCs) of healthy donors in patients infected with COVID-19 collected by apheresis. This allows us to collect cGMP PBMCs and immunomagnetic remove several types of undesirable cells including B, T and CD33+ cells with enrichment of NK cells that will be expanded in bioreactors with GMP culture media (AIM-V) supplemented with human AB serum and GMP grade IL-2, and IL-15. After quality control verification the final NK cell product will be resuspended in 300 mL saline solution for intravenous infusion. Initially, we will enroll in this study ten COVID-19 infected adult patients with moderate symptoms (NEWS 2 scale score>4). Consent forms will be signed by the patient before the therapy. Patients will be treated with three different infusions of NK cells 48 h apart with 1, 10, and 20 million cells/kg body weight. We will follow the patients for any adverse effect, clinical response and immune effects by flow cytometry including markers for NK cells expressing different markers (CD158b, NKG2A, and IFN-y). We anticipated that the release of IFN-y by exogenous NK cells could attract other immune cell populations to boost the immune response against COVID-19. *NCT04344548*

CONCLUSION & FUTURE DIRECTIONS

- This platform can serve as a medium to improve access by connecting patients to active clinical trials.
- Connect patients to active clinical trials globally.
- Form relationships with EMR organizations and integrate this platform to improve access & quality of care.