Part B: Information about the release application to be included on the public register

B1 The name and address of the applicant

ILiAD Biotechnologies, LLC
4581 Weston Road, Suite 260, Weston, FL USA 33331

B2 A general description of the genetically modified organisms in relation to which the application is being made

Genetically attenuated strain of Bordetella pertussis (BPZE1)

B3 The location at which the genetically modified organisms are proposed to be released

The planned clinical trial (Ph-2b) will be conducted at following sites in England and Wales:

Site Name	Address
Birmingham Children's Hospital NHS Foundation Trust	Steelhouse Lane, Birmingham, West Midlands, B4 6NH
Centre for Clinical Vaccinology and Tropical Medicine	Churchill Drive, Oxford University Hospitals, Oxford, OX3 7LE
Addenbrooke's Hospital	Liver Transplant Services; Hills Road, Cambridge, CB2 0QQ
Royal Manchester Children's Hospital	Neurology Department, Hospital Road, Pendlebury, Manchester, M27 4HA
Alder Hey Children's Hospital	Eaton Road, West Derby, Liverpool, Merseyside, L12 2AP
Bradford Royal Infirmary	Bradford Institute for Health Research, Duckworth Lane, Bradford, BD9 6RT
St George's Healthcare NHS Trust	Blackshaw Road, London, City of London, SW17 0QT
Leicester Children's Hospital	Infirmary Square, Leicester Royal Infirmary, Ward 14, Level 4, Leicester, Leicestershire, LE1 5WW
Bristol Royal Hospital for Children	Upper Maudlin Street, Bristol, BS2 8ED
St Mary's Hospital	South Wharf Road, Cambridge Wing, Urogynaecology Department, London, City of London, W2 1NY
University Hospital Southampton NHS Foundation Trust	Tremona Rd Mail point 218, Level C West Wing, NIHR Clinical Research Facility, Southampton, Hampshire, SO16 6YD
Children's Hospital for Wales	Children & Young Adults Research Unit Heath Park Cardiff CF14 4XW

B4 The purpose for which the genetically modified organisms are proposed to be released (including any future use to which they are intended to be put).

The GMO, BPZE1, is a live attenuated *B. pertussis* intranasal vaccine that is being studied in a clinical trial in school age children, as a follow-up to a previously successful Phase 2 study in 300 adults. The study has a goal of comparing BPZE1 to a current pertussis vaccine (Boostrix) to determine if BPZE1 can induce a robust systemic and a unique mucosal immunological response that can potentially protect school age children from *B. pertussis* infections. Current pertussis vaccines (called acelluar pertussis vaccines) do not protect against *B. pertussis* infection and therefore the ability to continue to transmit the bacteria to close contacts is a major cause of epidemic outbreaks (which occur every 3-5 years). Following BPZE1 intranasal administration, the live attenuated vaccine is transiently retained in the upper respiratory tract where it induces immunity. It cannot cause whooping cough due to the genetic changes as part of the vaccine design. The mucosal immunity induced by BPZE1 is targeted to reduce *B. pertussis* infection in immunised individuals, and by doing so can avert person to person transmission. The commercial opportunity is to gain regulatory licensure to vaccinate adults and children against pertussis, and eventually immunize infants.

B5 The intended dates of the release.

August 2021 – December 2022

B6 The environmental risk assessment.

The preliminary risk assessment for this study suggests there is an extremely low risk for potential environmental impact associated with administering the BPZE1 to study subjects. There is no known animal vector or reservoir for *B. pertussis* outside of humans; it does not exist in soil, on plants or in water. Its colonization is strictly limited to respiratory tract of humans and is non-invasive (e.g. does not enter blood or other organs), even in immune-compromised subjects.

B7 The methods and plans for monitoring the genetically modified organisms and for responding to an emergency.

Samples will be taken from the nose at key time points to ensure that the GMO has a limited survival and clears in all subjects. In all study subjects to date, the GMO has cleared within 45 days, with most subjects having evidence of no BPZE1 within 28 days following vaccination.

In summary, the GMO is readily sampled and identified, and the colonization and clearance behavior has been consistent and controlled over a typically < 28-day duration.

Efficient antibiotics (erythromycin) treatment can be administered. There is no known antibiotic resistance to the GMO. As such, the risk assessment shows a clear

and effective emergency response in the unlikely situation that the bacteria is transmitted to a non-study participant or the bacteria has prolonged colonization.