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22nd February 2021

Dear Kathryn,

Full title of study:	A phase III, 2 arm, multi-centre, open label, parallel-group randomised designed clinical investigation of the use of a personalised early warning decision support system with novel saliva bio-profiling to predict and prevent acute exacerbations of Chronic Obstructive Pulmonary Disease
Short Title:	Predict&Prevent AECOPD
REC ref:	19/LO/1939
Protocol Number:	833757
IRAS Project ID:	261576
Sponsor:	University of Birmingham

I am writing on behalf of the Chief Investigator, Professor Alice Turner, to inform you of a substantial amendment. The documents that have been added in the SA03 are listed below…

- **Patient Information Sheet V5.0 Vd22-Feb-2021**
- **Predict and prevent_v6.0 Vd22-Feb-2021**

This amendment is to clarify that patients can be recruited/ attend assessment appointments from patients homes and clinic as opposed to just in clinic, the trial itself already conducts home visits and with the current climate showing patients are concerned with attending hospital visits, this is the most appropriate course of action. The protocol and PIS has been amended to reflect this.

Amendments have also been made to remove the heavy reference to MHRA and medical device trials in the protocol. The the app is already CE marked and under the advice of MHRA and HRA the predict and prevent trial is classed as a non-IMP trial. Therefore, said references have been removed or replaced.
The predict and prevent trial also underwent a data protection audit which meant the PIS and Protocol needed to be amended so they match and are more clear about the movement of patient data.

Yours sincerely,

Dalbir Kaur on behalf of Professor Alice Turner

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