SYNOPSIS

Name of Sponsor/Company: **Royal College of Surgeons in Ireland**	Individual Study Table Referring to Part of the Dossier	*(For National Authority Use only)*
Name of Finished Product: **Humira**	Volume:	
Name of Active Ingredient: **adalimumab.**	Page:	

Title of Study:
Adalimumab (Humira) as add-on therapy in the treatment of patients with severe persistent therapy resistant asthma

Investigators:
Prof Richard Costello

Study centre(s):
Beaumont Hospital Dublin

Publication (reference)

N/A no report available as trial did not commence

Studied period (years): (date of first enrolment) (date of last completed) **N/A no report available as trial did not commence**	Phase of development: **Phase 2**

Objectives:

To determine whether patients with severe therapy resistant asthma respond to treatment with the biological disease-modifying anti-rheumatic drug (DMARD) Adalimumab (Humira)

Monitor safety of severe asthma patient being treated with the biological disease-modifying anti-rheumatic drug (DMARD)

Methodology:
Randomised placebo controlled double blind trial.

Number of patients (planned and analysed):
N/A trial did not commence

Diagnosis and main criteria for inclusion:

1. Male or female patient, over the age of 18 and under 65 years of age, at the date of consent
2. Diagnosis of Stage 4 Asthma, in accordance with the GINA guidelines
3. The patient has a documented diagnosis of asthma defined with a 12% reversibility of lung function by spirometry in the past 12 months
4. The patient has a screening FEV1 >=60 - 80% predicted normal value
5. Be receiving at least an inhaled corticosteroid dosage of fluticasone dry powder inhaler (DPI) >=500 ug/day or equivalent ex-valve dose during the 12 weeks prior to the screening visit

6.The patient has had at least one asthma exacerbation episode in the last 12 months. 7. The patient is capable of providing consent 8. The patient is willing to perform self-injection of the trial medication 9. The patient is fluent in and understands English
Test product, dose and mode of administration, batch number: **Humira solution for injection (subcutaneous use)**
Duration of treatment: **N/A**
Reference therapy, dose and mode of administration, batch number **N/A**

Name of Sponsor/Company: **Royal College of Surgeons in Ireland**	Individual Study Table Referring to Part of the Dossier	*(For National Authority Use only)*
Name of Finished Product: **Humira**	Volume:	
Name of Active Ingredient: **adalimumab.**	Page:	
Criteria for evaluation: Efficacy **N/A** Safety **N/A**		
Statistical methods: **N/A**		

Summary - Conclusions

N/A

Efficacy Results:

N/A

Safety Results:

N/A

Conclusion

This trial did not commence due to feasibility issues associated with funding.

Date of report: 30-Jan-2024