Bronchial Asthma
IDGN-BA-A16

I. INCLUSION AND EXCLUSION CRITERIA

INCLUSION CRITERIA

	Yes	No
1. Subject is diagnosed with Asthma according to: a. Presence of symptoms of airflow obstruction (2 or more of cough, wheezing, dyspnea). b. Airflow obstruction is at least partially reversible (demonstrated by spiromentry at any time - FEV1 increased by ≥15% following β-agonist inhalation) or evidence of bronchial hyperresponsiveness by metacholine challenge (demonstrated by PC20<8µg).	☐	☐
2. Age ≥ 12 years.		
3. Subject has less than 3 pack-years of smoking.	☐	☐
4. All 4 grandparents are of Ashkenazi Jewish origin as declared by the subject.	☐	☐
5. Subject or subject's legal representative has signed the informed consent form.	☐	☐

EXCLUSION CRITERIA

	Yes	No
1. Subject is diagnosed with any of the following list of Asthma differential diagnoses: a. Obstructions involving large airways: foreign body in trachea or bronchus; vocal cord dysfunction; vascular rings or laryngeal webs; laryngotracheomalacia, tracheal stenosis or bronchostenosis; enlarged lymph nodes or tumor. b. Obstructions involving small airways: viral bronchiolitis or obliterative bronchiolitis; cystic fibrosis; bronchopulmonary dysplasia. c. Other causes: recurrent cough not due to asthma (i.e. secondary to drugs such as angiotensin-converting enzyme [ACE] inhibitors); aspiration from swallowing mechanism dysfunction or gastroesophgeal reflux; chronic obstructive pulmonary disease (chronic bronchitis or emphysema); congestive heart failure; pulmonary embolism; pulmonary infiltration with eosinophilia; vasculitis involving the lungs and airways; post-transplant patients.	☐	☐
2. Subject is a known carrier of a blood transmitted infectious disease or suffers from conditions in which phlebotomy is contra-indicated.	☐	☐

Subject is eligible for the study, if all INCLUSION criteria are YES and all EXCLUSION criteria are NO.

INVESTIGATOR'S STATEMENT CONCERNING DATA VERIFICATION

I have verified the data entered in the Case Report Form and have determined that it is complete, accurate and compatible with the source documents.

Investigator's name (printed)	Investigator's signature	Day	Month	Year
_____	_____	☐☐ /	☐☐ /	☐☐

Where appropriate mark like this ☒ (not like this ☑)

SUBJECT BARCODE STICKER

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II. DEMOGRAPHICS

1. Sex: ☐ **Male** ☐ **Female**

2. Year of birth: ☐☐☐☐

3. Country of birth: _____

4. Year of immigration: ☐☐☐☐

5. Height*: ☐☐☐ cm

6. Weight*: ☐☐☐ kg

* If measurements cannot be carried out, subject's declaration is sufficient.

III. FAMILY HISTORY

1. Mother	Country of birth	**2. Father**	Country of birth
1.1 Mother:	_____	2.1 Father:	_____
1.2 Grandfather:	_____	2.2 Grandfather:	_____
1.3 Grandmother:	_____	2.3 Grandmother:	_____

3. Blood relatives:

3.1 Specify total number of siblings (including patient): ☐☐

3.2 For close family members **known to suffer** from the following conditions, please answer the questions regarding their medical history:

	Childhood onset asthma (<=12 yrs.)	Adult onset asthma	Skin atopy/eczema	Allergic rhinitis	Migraine or recurrent headaches
Mother	☐	☐	☐	☐	☐
Father	☐	☐	☐	☐	☐
Sib 1	☐	☐	☐	☐	☐
Sib 2	☐	☐	☐	☐	☐
Sib 3	☐	☐	☐	☐	☐
Child	☐	☐	☐	☐	☐

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IV. CLINICAL CHARACTERISTICS

1. Age at diagnosis or onset of symptoms (the earliest of the two): ☐☐

2. Diagnosis was made by (mark one or both):

a. FEV1 improvement of more than 15% after inhalation of a β adrenergic agonist. ☐

b. Bronchial hyperresponsiveness demonstrated by a PC20<8μ gram of methacholine. ☐

3. Last abnormal pulmonary function tests:

a. FEV1% Pre-beta agonists ☐☐

b. FEV1% Post-beta agonists ☐☐

Regarding asthma severity (before treatment, excluding inhaled short acting agents):

4. Symptoms occur at a frequency of:

a. 2 episodes per week or less ☐

b. More than 2 episodes per week but not daily ☐

c. Daily ☐

	Yes	No
5. Do exacerbations limit daily activity?	☐	☐
6. Does the patient use inhaled short acting β-agonists daily?	☐	☐

7. Specify the number of daily puffs of inhaled short acting agent: ☐☐

8. The frequency of night-time symptoms is (mark only one):

a. 2 episodes per month or less ☐

b. More than 2 episodes per month but less than 1 episode per week ☐

c. More than 1 episode per week ☐

d. Almost every night ☐

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IV. CLINICAL CHARACTERISTICS (cont.)

	Yes	No	Unknown
9. Is PEF / FEV1% normal between attacks?	☐	☐	☐
10. Can a precipitating / aggravating factor be identified?	☐*	☐	
***If yes, specify (mark as many as appropriate):**			
a. Environmental indoor (e.g. mites)	☐		
b. Exercise	☐		
c. Infection	☐		
d. Occupational chemicals / allergens	☐		
e. Emotions	☐		
f. Drugs (including aspirin and NSAIDs)	☐		
g. Food / food additives / preservatives	☐		
h. Seasonal changes	☐		
i. Changes in weather	☐		
j. Menses / pregnancy	☐		
k. Other, specify: _____	☐		
Other:			
11. Does the patient suffer from allergic rhinitis / chronic sinusitis?	☐	☐	
12. Does the patient suffer from frequent skin allergies / eczema?	☐	☐	
13. Does the patient suffer from migraine headaches?	☐	☐	

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V. MEDICATIONS

1. Regarding long-term therapy (if relevant), specify the drug / drug combination that gives the patient the best improvement / control of the disease:

Short-acting agents only ☐

Long-acting β agonist ☐

Inhaled corticosteroids at a low-medium dose ☐

Inhaled corticosteroids at a high dose ☐

A leukotrein modifier ☐

Theophylline ☐

Systemic steroids-intermittently* ☐

Systemic steroids-continuously** ☐

*If treated intermittently with systemic steroids, specify the number of courses given over last year: ☐☐

**If treated continuously, specify the average prednisone equivalent dose: ☐☐

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