

# Study of Immune Globulin Intravenous (Human) GC5107 in Pediatric Subjects With Primary Humoral Immunodeficiency

**Status:** Recruiting

## Eligibility Criteria

**Age:** 2 years to 16 years old

This study is NOT accepting healthy

**Healthy Volunteers:** volunteers

### Inclusion Criteria:

- Subject must be  $\geq 2$  to  $< 17$  years of age, at the time of signing the informed consent
- Pediatric subject has a confirmed and documented clinical diagnosis of Primary Humoral Immunodeficiency, including hypogammaglobulinemia or agammaglobulinemia
- Subject who has received 300
- 900 mg/kg of IGIV therapy at 21 or 28 day intervals for at least 3 months prior to this study
- Subject who has at least 2 documented plasma IgG trough level of  $\geq 500$  mg/dL at two infusion cycles (21 or 28 days) within 12 months prior to enrollment
- Subject who is willing to comply with all requirements of the protocol

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### Exclusion Criteria:

- Subject who has a history of clinically significant reactions or hypersensitivity to IGIV or other injectable forms of IgG
- Subject who has IgA deficiency and is known to have antibodies to IgA
- Subject who has secondary immunodeficiency
- Subject who has participated in another clinical study (other than an IGIV study) within 3 weeks prior to screening
- Subject who has been diagnosed with dysgammaglobulinemia or isolated IgG subclass deficiency or isolated IgA deficiency, or who has clinically significant impairment of cellular or innate immunity at the discretion of the Investigator
- Subject who has received blood products other than human albumin or human immune globulin within 6 months prior to enrollment

## Conditions & Interventions

### Interventions:

Biological: GC5107

### Conditions:

Primary Immune Deficiency

## More Information

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**Principal Investigator:** Zhao, Wei

**Phase:** Phase 3

### IRB

**Number:** HM20021702

**System ID:** NCT04565015

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