

"An overview study of Intravenous Immunoglobulin and global market scenario of IVIG"

Ankit khandelwal



Ankit Khandelwal



ankit@plasmagen.in



+918233755305

Table of content

1.

ABOUT COMPANY

2.

Usage of IVIG

3.

Research Methodology

4.

Global Market of IVIG

5.

INDIA Market of IVIG

6.

CONCLUSIONS



About PlasmaGen

Who we are....

PlasmaGen BioSciences is Indian Biopharmaceutical organization specializing in Plasma Protein Therapy and dedicated towards improving the health and quality of life of patients in India and SAARC regions.

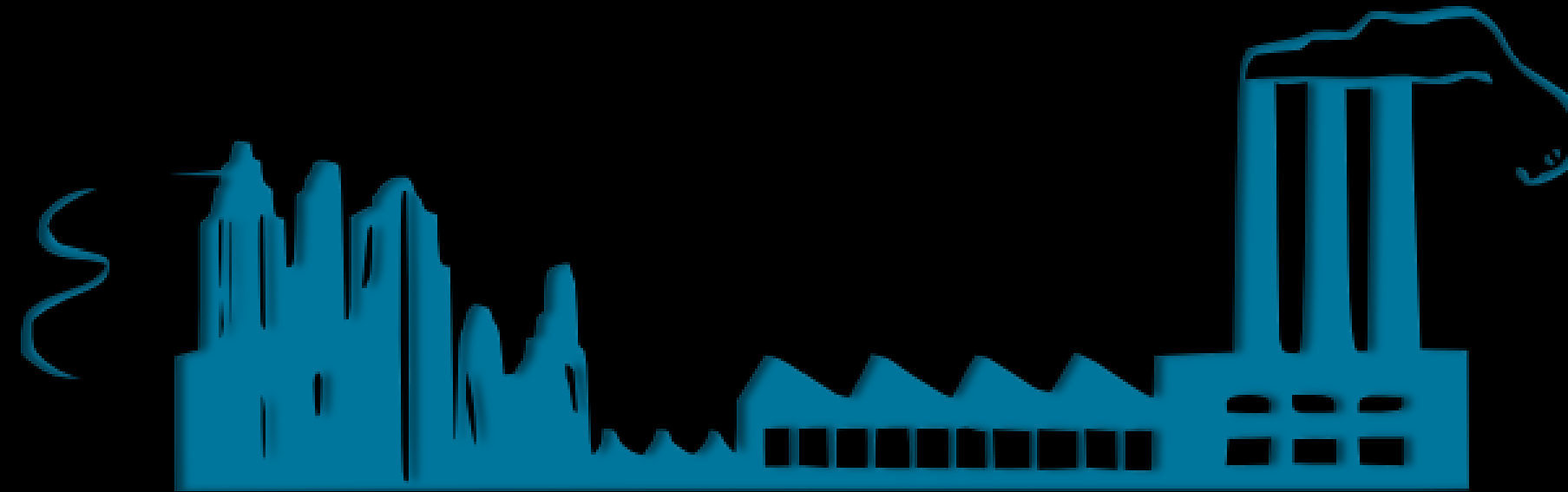
PlasmaGen BioSciences has widest basket of Plasma products in India



Pristine Quality & Spotless Delivery



The Future....



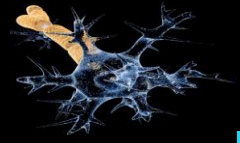
As logical extension of our work and effort, under our new investment plan,

PlasmaGen is all set to

The establishment of its own manufacturing facility in Bangalore, India...

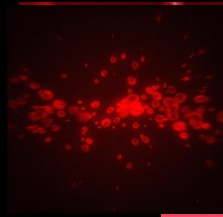
This would be one small step but important one towards achieving self- sufficiency in Plasma Products arena in India...

IVIg usage portfolio



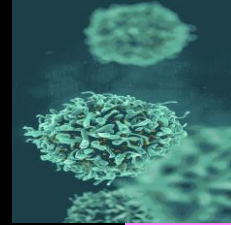
Neurology

- Guillain Barre syndrome
- Multifocal motor neuropathy
- Chronic inflammatory demyelinating polyneuropathy
- Dermato-myositis
- Inflammatory myopathies
- Myasthenia gravis



Haematology

- Immune thrombocytopenia
- Post bone marrow transplant
- Myeloma
- Chronic lymphocytic leukaemia
- Immune neutropenia
- Immune haemolytic anaemia



Immunology

- Primary antibody deficiencies (XLA, CVID, HIGM, WAS and others)
- Secondary antibody deficiencies (myeloma, CLL (RCL), drugs and other causes)



Dermatology

- Kawasaki syndrome
- Dermato myositis
- Toxic epidermal necrolysis
- Blistering diseases
- Immune urticaria
- Atopic dermatitis
- Pyoderma gangrenosum



Nephrology, Rheumatology & others

- Vasculitis
- Systemic lupus erythematosus
- Streptococcal toxic shock syndrome
- Birdshot retinochoroidopathy
- Autoimmune uveitis
- Mucous membrane pemphigoid



Research Methodology



MS-Excel 2016



5th February to 4th May



The secondary data was used. Secondary data for competitor analysis and market trends

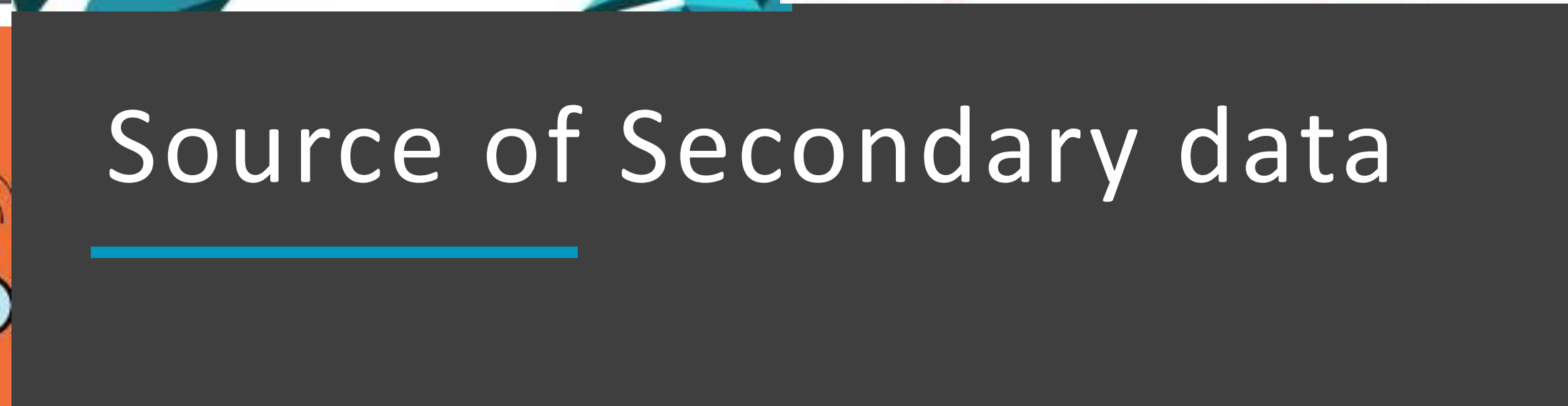
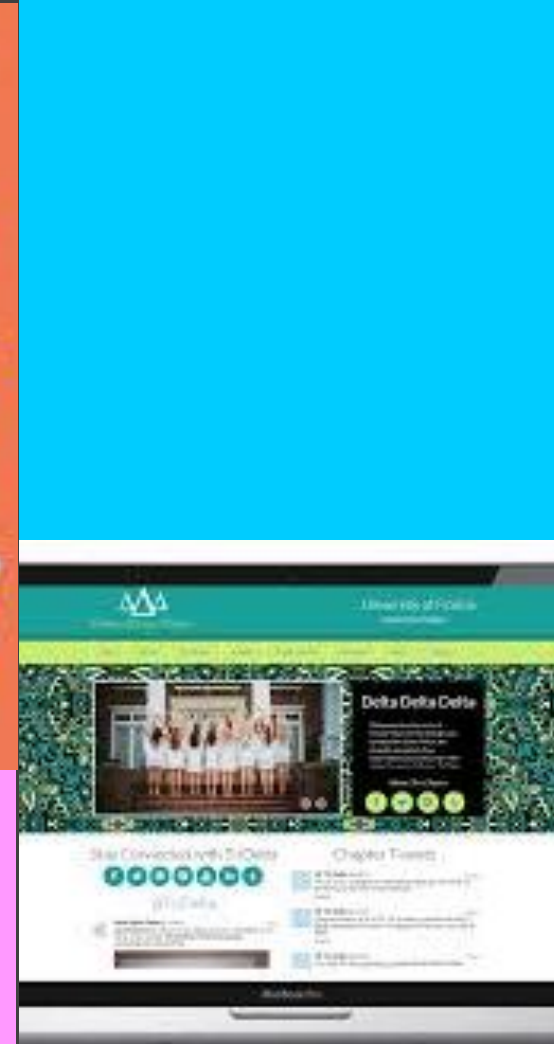


Descriptive study

Source of Secondary data:

Secondary Research we refer a broad array of industry sources for our secondary research, which typically include; however, not limited to:

- **Company annual reports, company websites, & financial reports** and investor presentations for competitive scenario and shape of the industry
- **Scientific** and technical writings for **product information** and related preemptions
- **Authentic new articles**, web-casts and other related releases for market evaluation
- \ Internal and external proprietary databases, key market indicators and relevant press releases for market estimates and forecast



Objectives:

- To understand the wide usage of IVIG in different indications.
- To understand the global market of IVIG.
- To determine the market share of different brands of medicine Available in market.
- To understand the global market trends of IVIG



Usage of IVIG

PlasmaGlob is a brand of Normal **Human Immunoglobulin** for Intravenous use manufactured from Human Plasma

Indications:

- ✓ **Guillain-Barré syndrome**
- ✓ Chronic Inflammatory Demyelinating Polyneuropathy
- ✓ Primary Immunodeficiency
- ✓ B-cell Chronic Lymphocytic Leukemia
- ✓ Immune Thrombocytopenic Purpura
- ✓ Kawasaki syndrome



What is GBS..?

❖ **polyradiculoneuropathy**

INTRODUCTION

- ✓ Autoimmune in nature
- ✓ Acute
- ✓ Frequently severe
- ✓ Fulminant

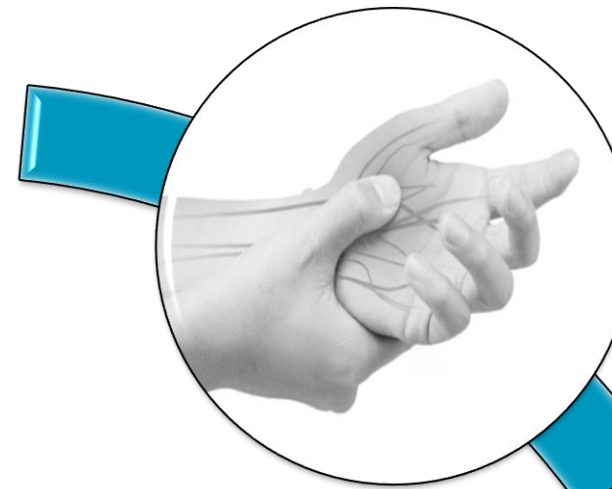
A decorative graphic on the left side of the slide. It features a large teal circle containing the text 'Types of GBS'. Surrounding this circle are several smaller circles in cyan, magenta, pink, orange, and light blue. In the top right corner, there is a light blue triangle pointing towards the center.

Types of GBS

1. AIDP
2. AMAN
3. AMSAN
4. Miller Fisher syndrome

Signs & symptoms

Signs and Symptoms



Numbness and tingling in hand and feet



Distal progression

- muscle weakness, diminished reflexes.

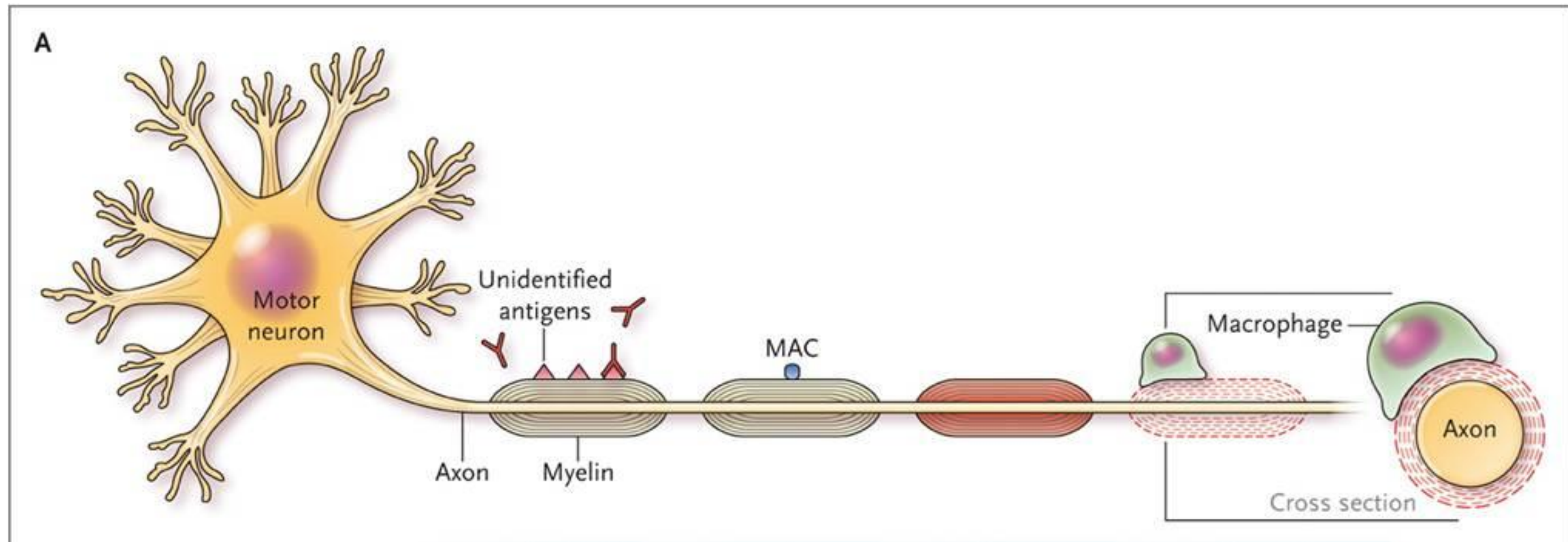


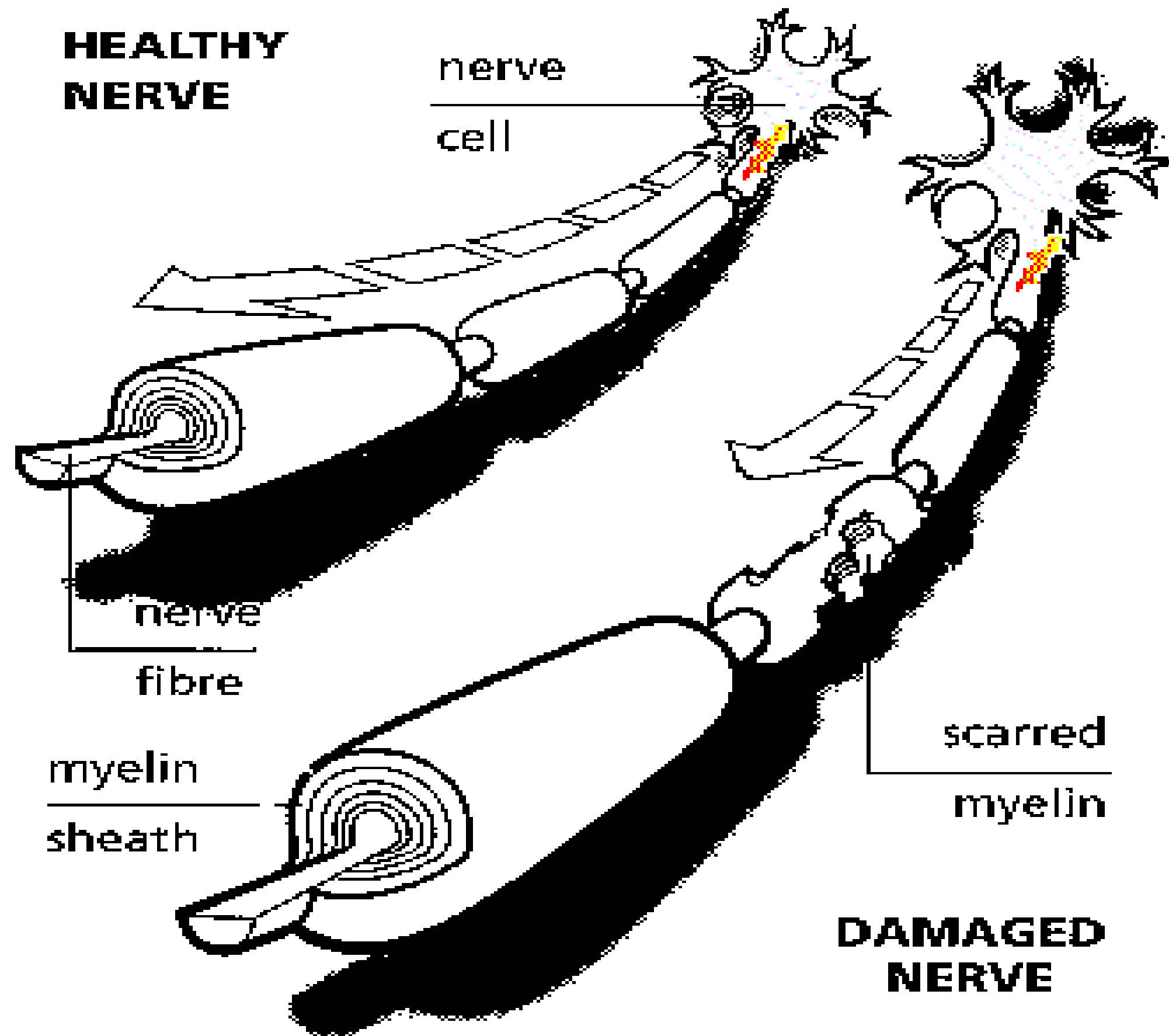
progression to trunk, face and cranial nerve, resulting in difficulty chewing, speaking and facial expression.

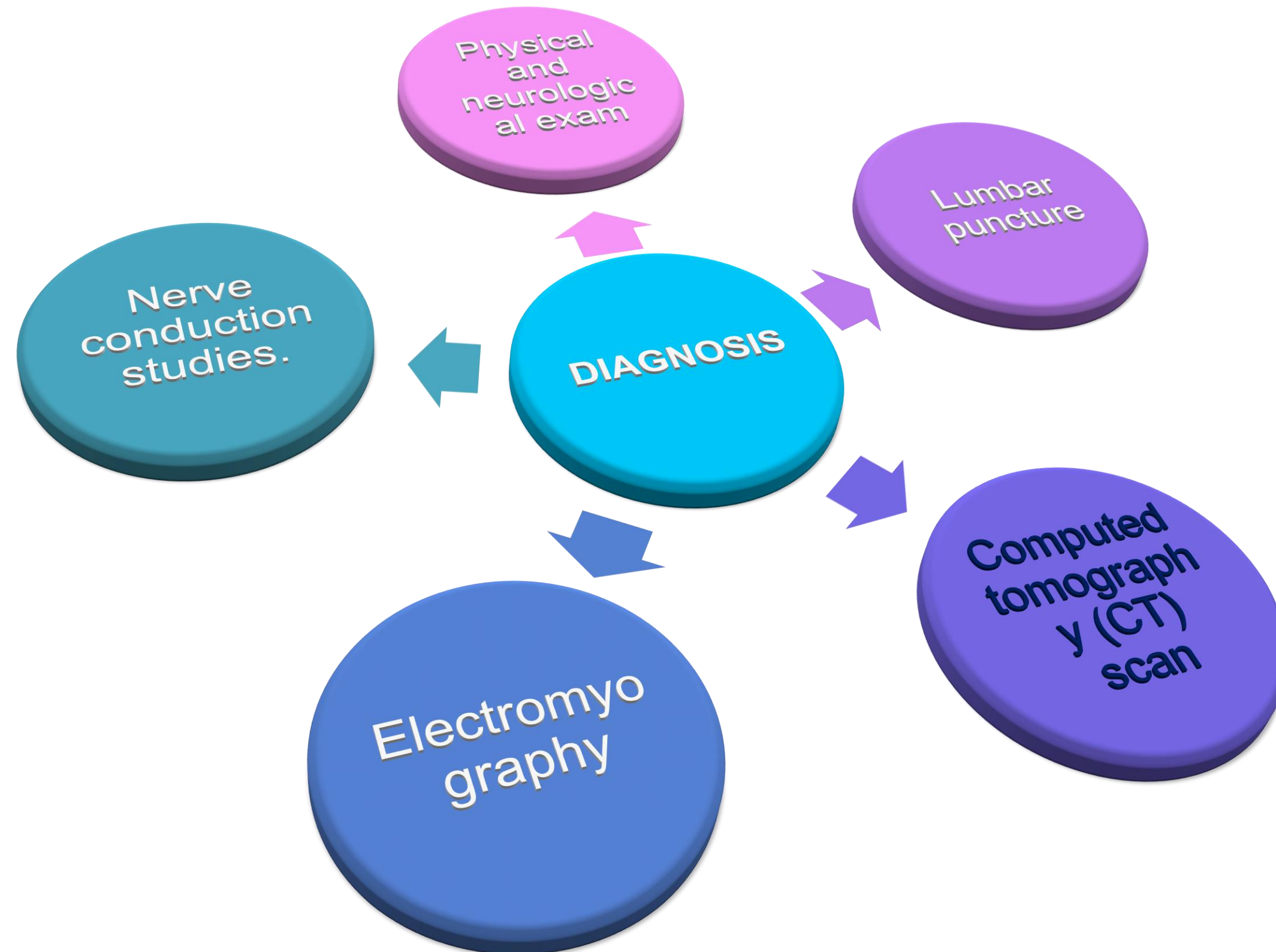


Deep aching pain/hypersensitivity to touch. Dysfunctioning in respiration process

1. Pathophysiology Of AIDP







Treatments



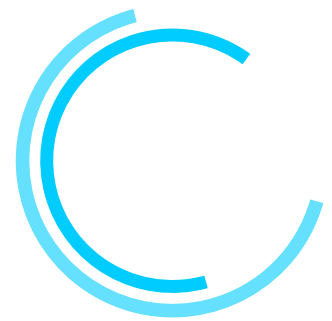
IVIG

Inhibition of complement
– mediated damage

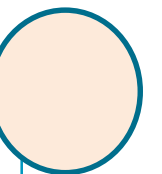
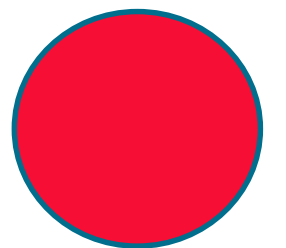
Reduced Nerve injury

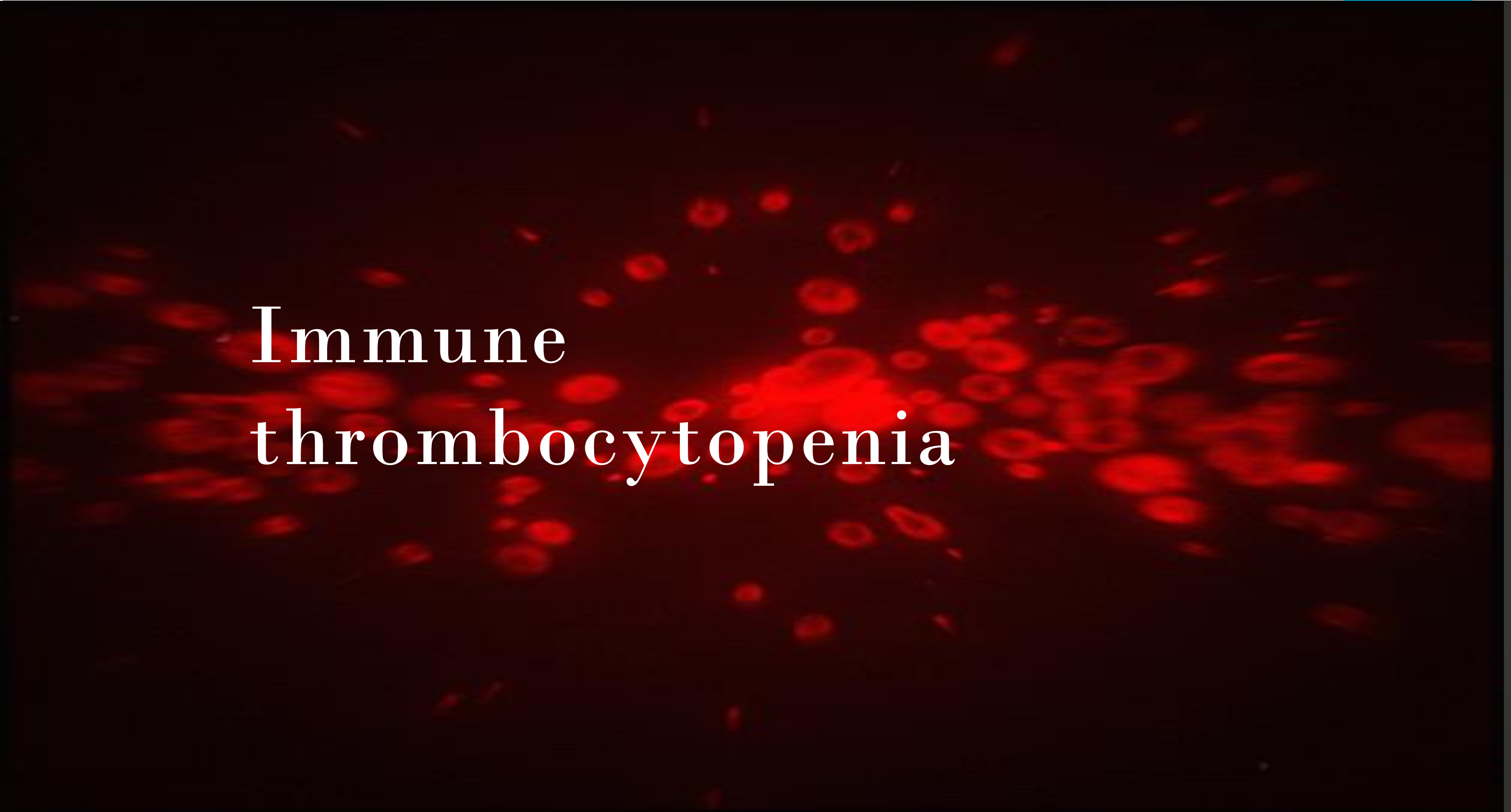
**Dose -
0.4gm/kg for 5
days**

2. Plasma Exchange (Plasmapheresis)



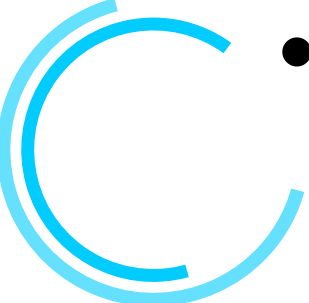
- In this therapy only plasma is collected ,blood cells are put back into body
- Plasmapheresis may work by riding plasma of certain antibody that contribute to the immune system's attack on the peripheral nerves

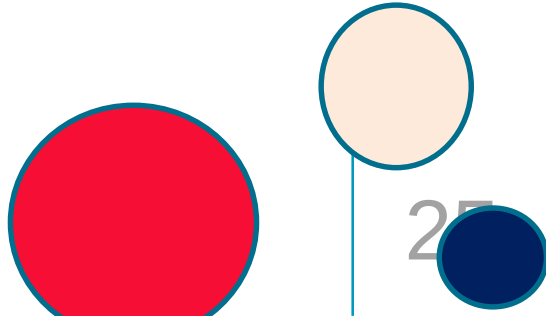


A microscopic view of numerous red blood cells, appearing as bright red, biconcave discs against a dark background. The cells are scattered across the frame, with some in sharp focus and others blurred in the background.

Immune thrombocytopenia

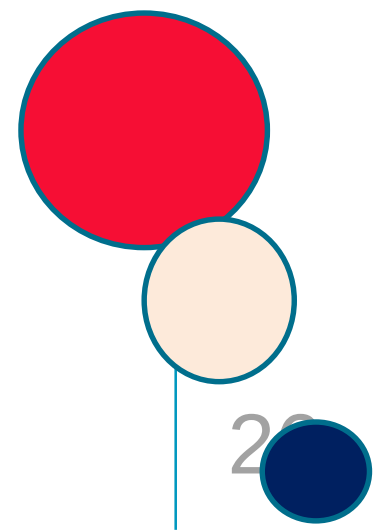
1. About ITP.....

- 
- ITP is an autoimmune disorder.
 - ITP may occur when the immune system mistakenly attacks platelets.
 - It is mainly seen in children where it is usually acute, and also occurs in adults, where it is usually chronic in nature.
 - A normal platelet count is b/w 150,000-400,000/microliter of blood. If someone has a platelet count lower than 100,000/microliter of blood with no other reason for low platelets, that person is considered to have ITP.

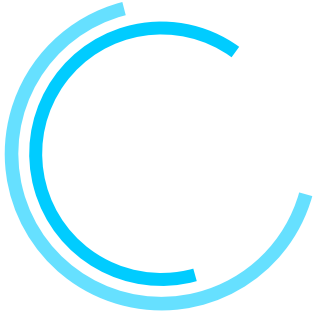


1. Difference b/w aITP & cITP

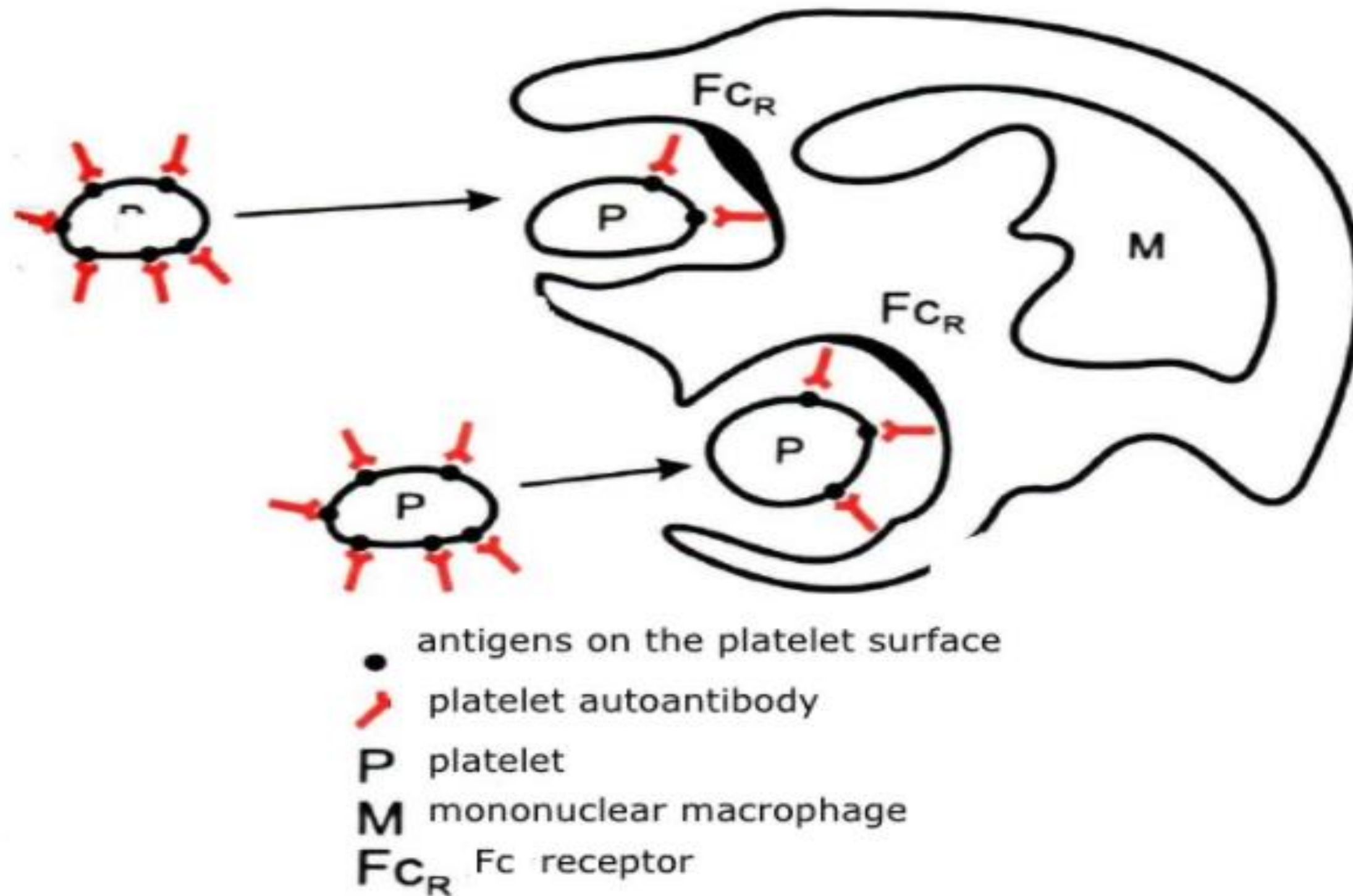
	aITP	cITP
age	A peak incidence between 2 and 5 years of age	More frequent in adolescents and young adults
onset	relatively acute	relatively chronic
degree of hemorrhage	relatively severe	relatively mild
course of disease	≤ 6 months	> 6 months
platelet count	Mostly, $< 20 \times 10^9/L$	Commonly $(30 \sim 80) \times 10^9/L$
Numbers of megakaryocytes of bone marrow	normal or increased	increased markedly



Cause

- 
- In some people thrombocytopenia is caused when, the immune system **mistakenly attacking and destroying platelets**. If the cause of this immune reaction is unknown, the condition is called idiopathic thrombocytopenic purpura.
 - **Inadequate platelets productions**

Pathophysiology



Sign & Symptoms

Excessive bruising (purpura)

Superficial bleeding into the skin that appears as a rash of pinpoint-sized reddish-purple spots , usually on the lower legs

Bleeding from the gums or nose

Blood in urine or stools

Unusually heavy menstrual flow

Diagnosis test

S/no	TEST	CHECK	PRICE
1.	CBC	Count of blood cells & platelets	350
2.	Bone marrow exam	identify the cause of a low platelet count,	950
3.	Blood coagulation test	To check bleeding time	—

1

Corticosteroids

3

Anti-D
immunoglobulin

2

IVIG

4

Splenectomy

Treatments

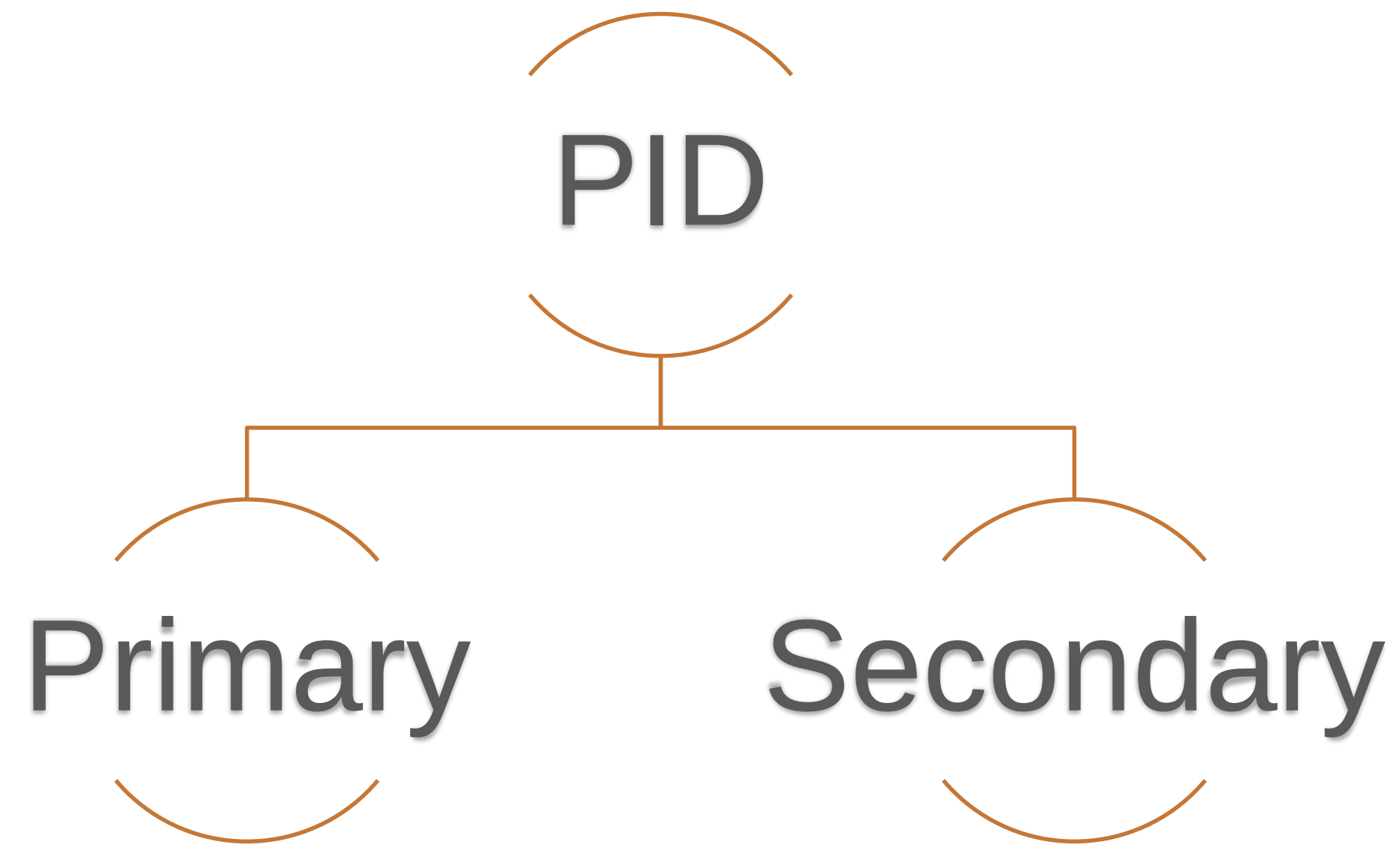


Primary immunodeficiency diseases

Introduction

- A group of disorders characterized by an impaired ability to produce normal immune response.
- Most of these disorders are caused by mutations in genes.
- PID Mainly occur when a part of immune system is either absent or not functioning properly.
- There are 300 rare disease out of which 150 gets identified.

Types of PID



Immune Deficiencies

Primary



Parents



Disease-carrying gene(s)



Child born with IgA deficiency, CVID, SCID, or other primary immune deficiency

Secondary



- Intravenous (IV) drug abuse, unsafe sexual activity, and other risk behaviors
- Malnutrition
- Chronic diseases (such as diabetes)
- Medications (such as corticosteroids)



Development of AIDS or other secondary immune deficiency



Impaired (weakened) immune response

Symptoms...

- new ear infections
- serious sinus infections
- pneumonias
- Weight loss
- Recurrent, deep skin or organ abscesses
- Persistent thrush in mouth or fungal infection on skin
- A family history of Primary Immunodeficiency

Treatments..

- The long-term goal of IVIG therapy is to render the patient infection free, to the greatest extent possible.
- Treating PID with IVIG preserves organ function, improves quality of life, prevents infection-related death, and increases lifespan.
- Dose - **0.4-0.6 gm/kg every 3-4 weeks.**

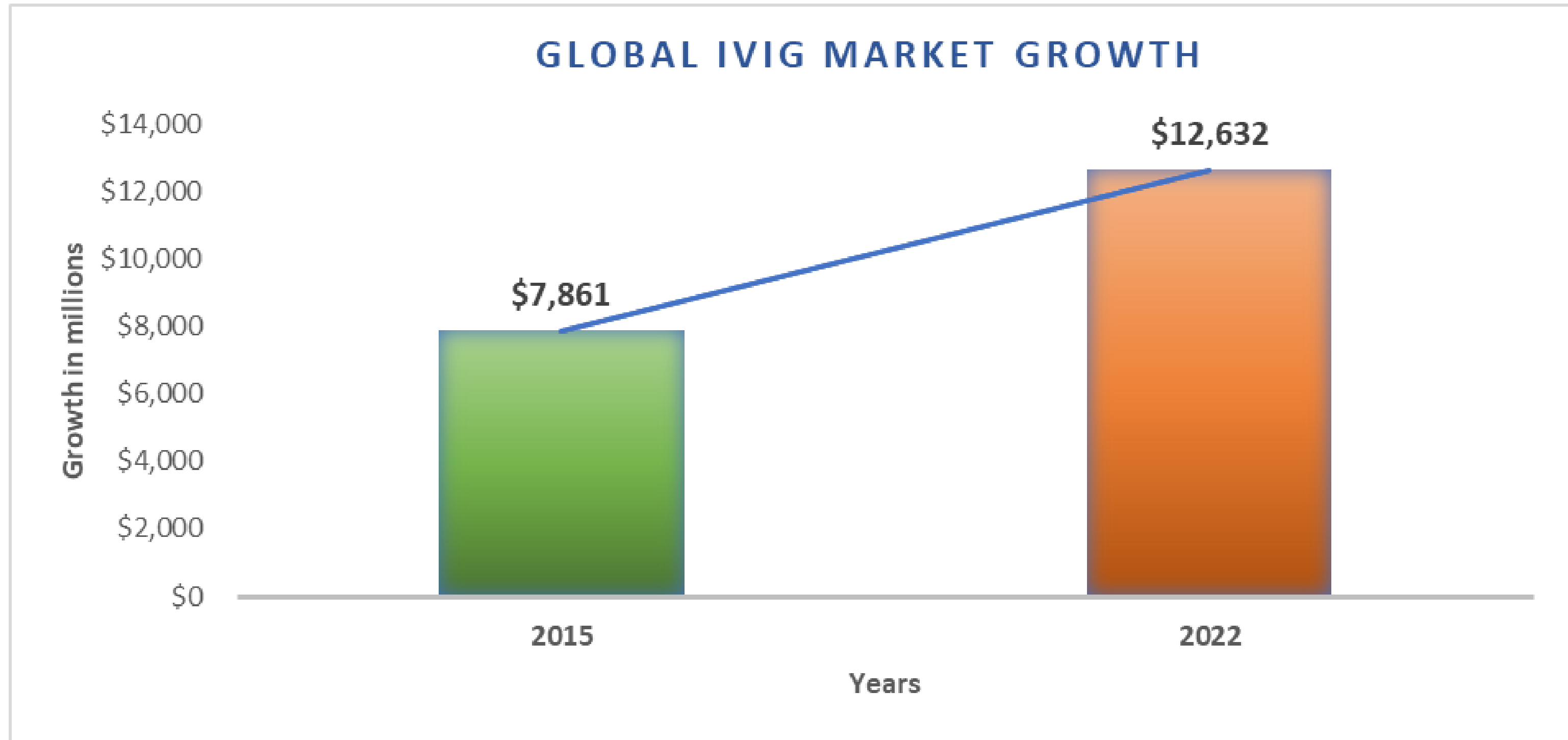
Global Market of IVIG

- Geographically, the IVIG market segments across four geographies namely, North America, Europe, Asia-Pacific, and LAMEA (Latin America, Middle East, and Africa).
- Various regulatory authorities such as USFDA, EMA, the Japanese Pharmaceuticals and Medical Devices Agency, the Australian Therapeutic Goods Administration, and Health Canada, regulate the manufacture, distribution, and sale of IVIG in their respective regions.

IVIG Market Based on Geographic



Expected IVIG Market Growth...



- The global IVIG market, by geography, is expected to grow from **\$7,861.5 million** in 2015 to **\$12,632.5 million** by 2022, at an estimated CAGR of 7.1% from 2016 to 2022.
- North America leads the IVIG market as majority of the multinational players belong to this region.
- LAMEA is expected to grow at a high CAGR of 10% growing to the increase in preference of IVIG therapies

NORTH AMERICA

- The North America **PID market** was valued at **\$1678 million** in 2015 and is expected to reach \$2661 million, growing at a CAGR of 6.1% during the analysis period.
- The U.S. National library of Medicine and the National Institute of Health published a report, in 2012, about 6 million patients suffered from PID globally and is expected to grow further, representing the potential growth for the treatment of hypogammaglobulinemia in the coming years
- North America held the largest regional market share in terms of revenue in 2014 due to the presence of:
 - ✓ a well-regulated healthcare system
 - ✓ the larger pool of target population
 - ✓ high patient awareness pertinent to the plasma protein product.

CHINA

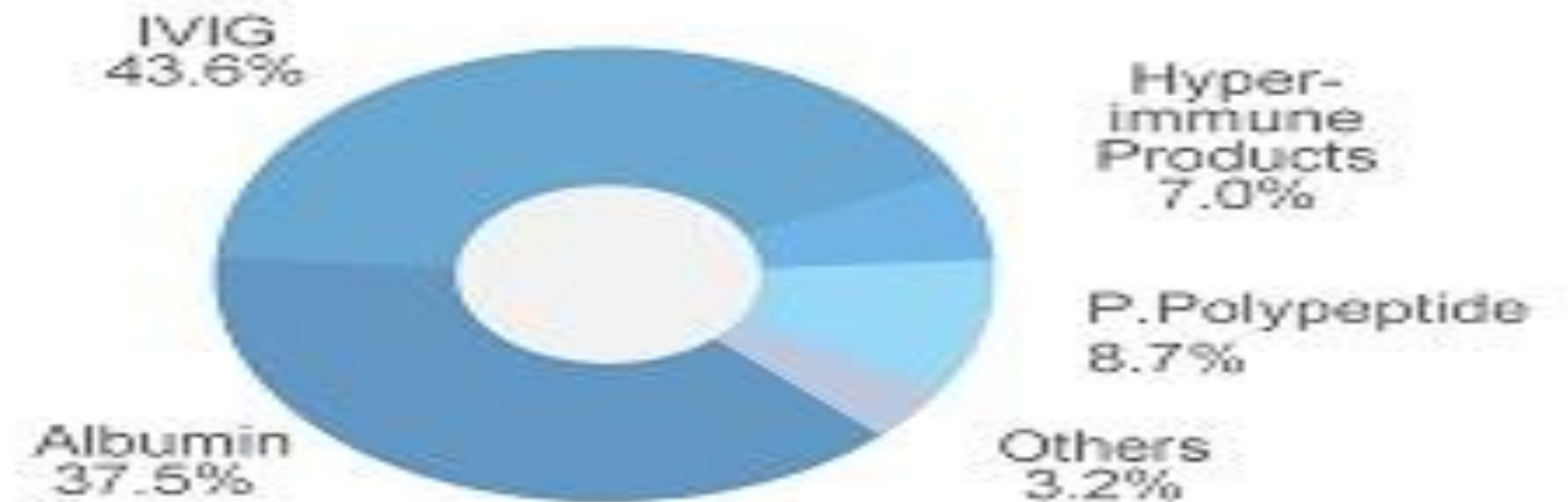


Source: The Marketing Research Bureau, Inc. and Company estimates

CHINA

CBPO Sales Breakdown by Product

(9M'15 Sales %)



3rd Largest Domestic Player in China Albumin market

(Based on 9M'15 Sales)



Largest Player in China IVIG market

(Based on 9M'15 Sales)

Source: Company estimates based on the public release of government batch approval data.
1. Includes sales attributable to Xi'an Huitian, in which we hold a 35% non-controlling interest.

CHINA

S/No.	Company Name
1.	China Biological Product.inc
2.	Guizhou Taibang Biological Product Co.
3.	CSL Limited
4.	Haulan Biological Engineering inc
5.	Octa Pharma
6.	Sichuan Yuanda Shuyang Pharmaceuticals
7.	Omrix Biophaarmaceuticals Ltd.
8.	Biotest AG

EUROPE

- The EUROPE IVIG market was valued at \$2150 million in 2015 and is expected to reach \$3000 million, growing at a CAGR of 6 % during the 2015 – 2022.
- In EUROPE, the French IVIG market was valued at \$299 million in 2015, and is expected to reach \$474 million by 2022, with a CAGR of 6%

Globally Key players operating in the IVIG market:



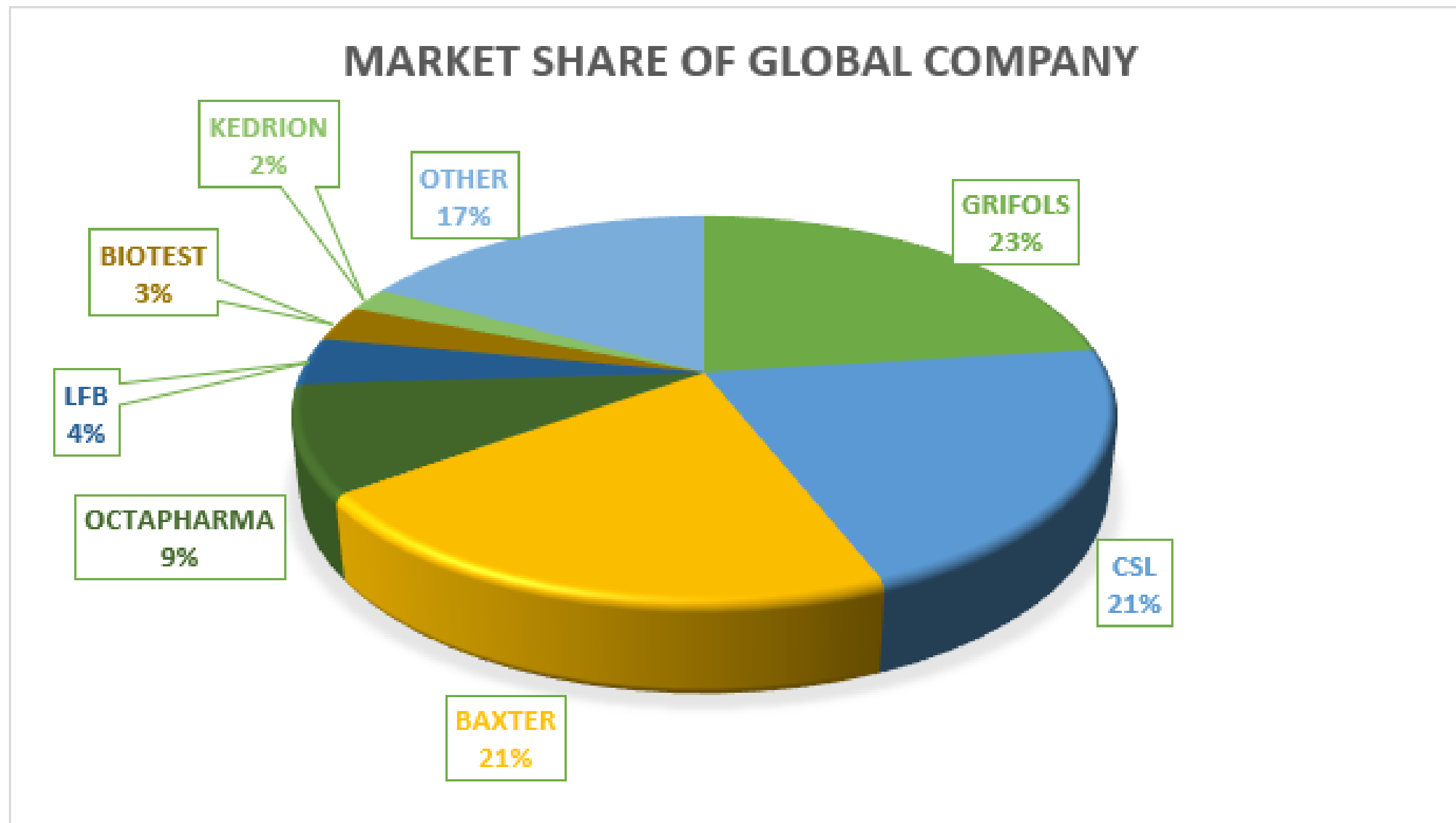


Figure 12: IVIG Market share of Global Companies

Product available in
Global Market:

S./no	COMPANY	BRAND NAME	CONCENTRATIONS	SIZES
1.	CSL Behring	Carimune NF	3%,6%, 9%, 12%	3g, 6g, 12g
2.	Grifols	Flebogamma 5% DIF	5%	2.5g, 5g, 10g, 20g
3.	Grifols	Flebogamma 10% DIF	10%	5g, 10g, 20g
4.	Shire	Gammagard	5%, 10%	5g, 10g
5.	Bio Product Lab.	Gammaplex 5%	5%	5g, 10g, 20g
6.	Bio Product Lab.	Gammaplex 10%	10%	5g, 10g, 20g
7.	Octapharma	Octagam 5%	5%	1g, 2.5g, 5g, 10g, 25g
8.	Octapharma	Octagam 10%	10%	2g, 5g, 10g, 20g
9.	CSL Behring	Privigen	10%	5g, 10g, 20g, 40g

Global sales of IVIG based on regions

1 North America

46%

2 Asia + Pacific

18%

3 LEMA

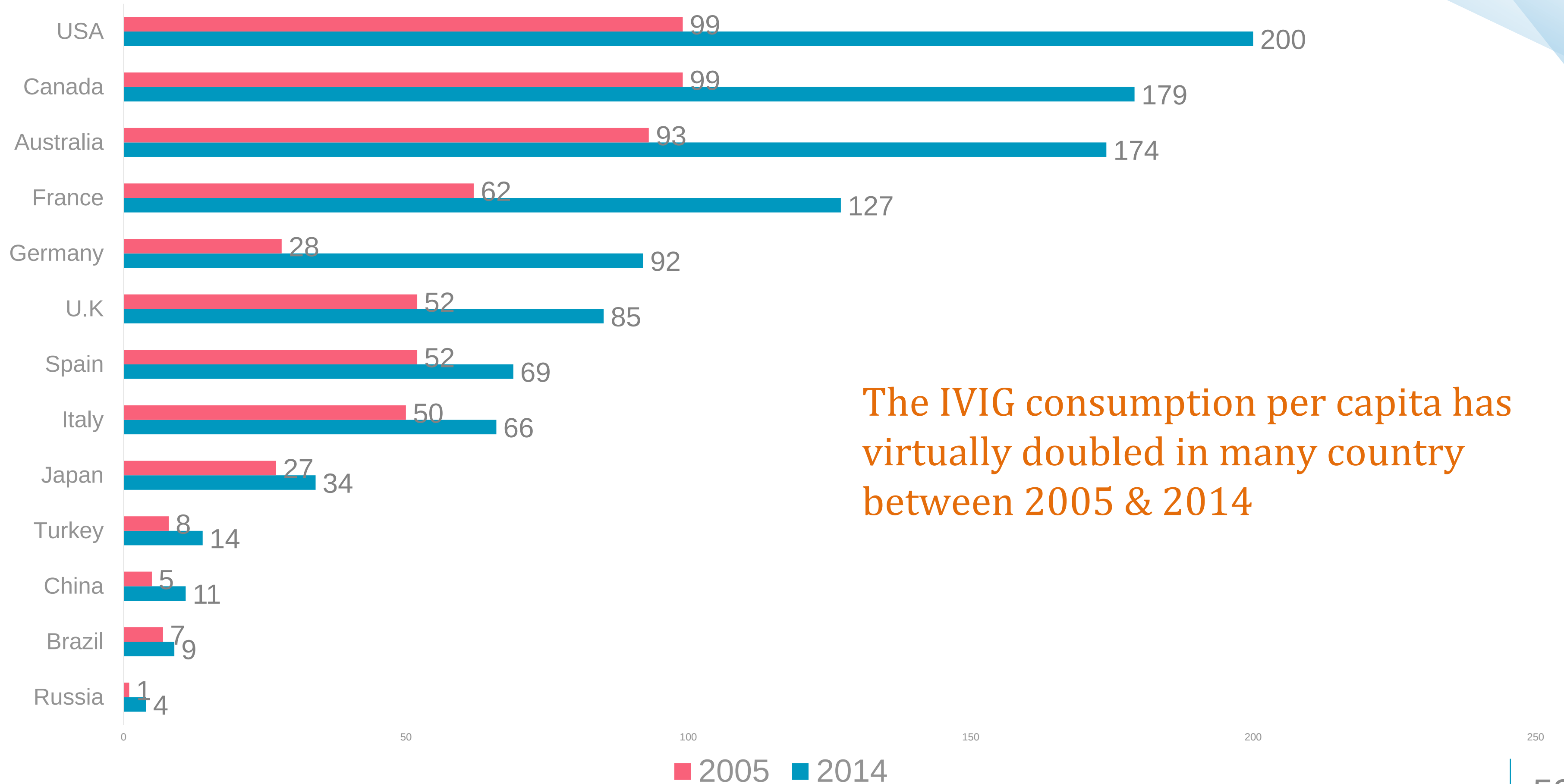
7%

4 EUROPE

28%



KG per Million People



IVIG Market Based on Geographic





INDIA

- India is the seventh largest country in terms of area and the second most populous country in the world.
- Plasma is one such resource, which India could have in abundance, but its potential is still unrealized.
- India collects about 10 million of blood at more than 2700 blood banks across the country.
- These blood banks are in public, private, charitable, and hospital settings.

Indian Scenario

- India needs about 900,000 liters of plasma proteins per year. The overall demand of various plasma derived products are depicted in the table 3 Import of size of these products in year 2014-15 and their cost.

Table 3: overall current demand of albumin , coagulation factor VIII and IX , and intravenous immunoglobulin			
Albumin	IVIG	Factor VIII	Factor IX
8-10 lac vials	3 -4 lac vials	80-100 million IUs	10-15 Million IUs
20 gm/ 100 ml	5 gm/100 ml	250 IUs	500 IUs

In INDIA IVIG market segment namely:



Hematology



Immunology



Dermatology



Neurology



Rheumatology

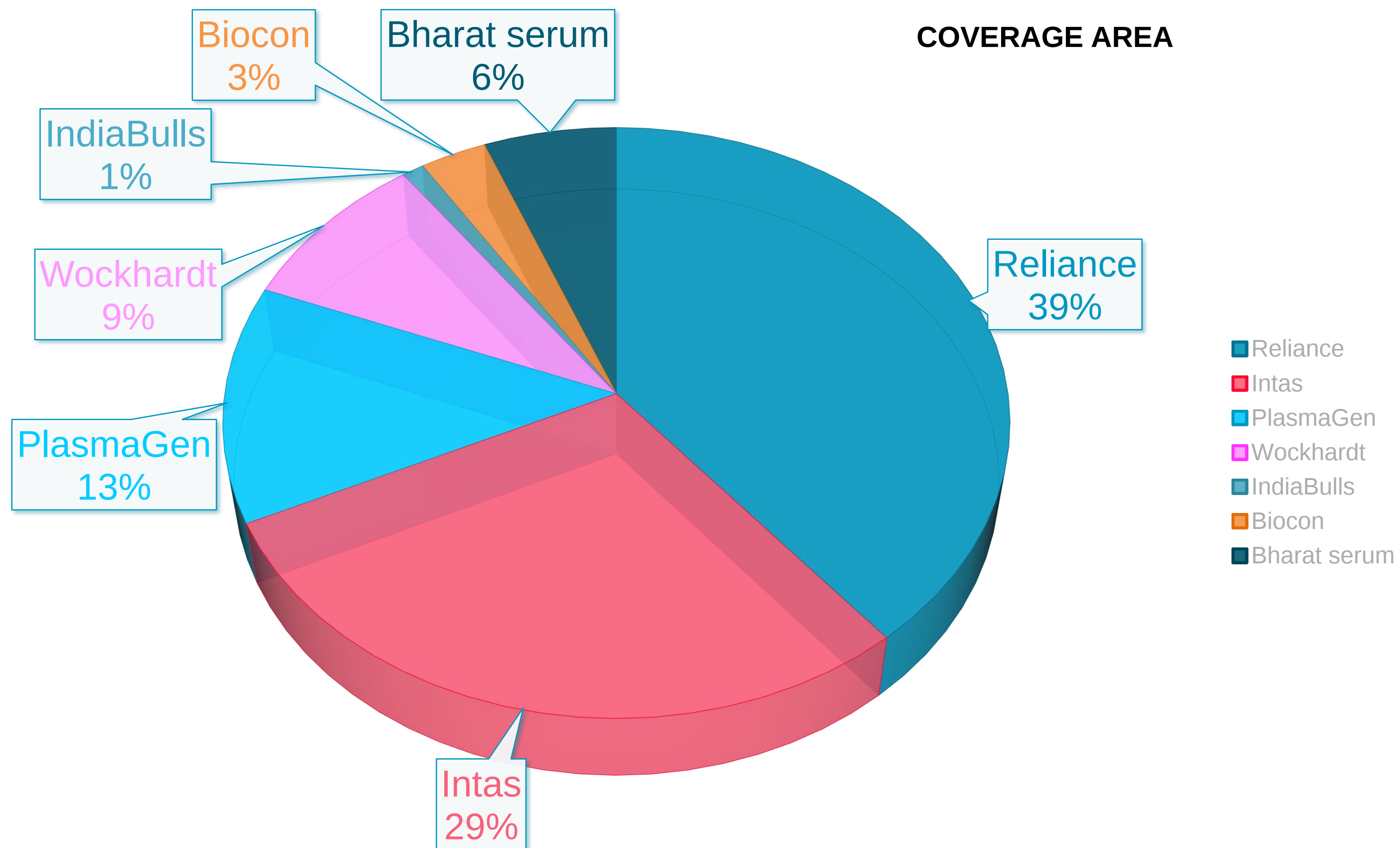


Pediatrics



Oncology





Company	Brand name	Strength	MRP	Market share in unit(Per Month)	Market share in Crore
Reliance	Immunorel	5%,	₹13507	5250	7.71
Intas	Globucel	5%, 10%	₹14697	3245	4.79
PlasmaGen	PlasmaGlob	5%,	₹17061	1700	2.49
Wockhardt	globuwok	5%,	₹17036	1365	2.00
Bharat Serum	Gamma IV	5%,	₹13334	720	1.05
Biocon	Ivnex	5%,	₹13190	345	0.50
Emcure	Emglobulin	5%	₹15697	90	.013
GSK	Seroglobulin	5%	₹14697	150	0.22
India bulls	Immuglo	5%	₹13507	225	.33

Recommendations:

- **Price** is the important criteria for making brand successful, so price should be economical as well because many doctors rely on price factor because cost of IVIG therapy is very high especially in government hospital.
- The Neuro physician and Hemato oncologist are using IVIG in rare disorder so the companies should be actively promote their product to these doctors.
- **Medical Literature** should be provided to doctors to make them aware about the recent advance in plasma product and usage in newer indications.
- According to the current market, the global IVIG market is segmented based on its application in the treatment of several conditions, i.e., CIDP, ITP, PID, Secondary Immunodeficiency in Chronic Lymphocytic Leukemia, Pediatric Human Immunodeficiency Virus (HIV) infection, Kawasaki disease, Specific antibody Deficiency, Acquired Hypogammaglobinemia, Myasthenia Gravis so we can easily segregate the market and segregate the potential customers like hematology, neurology, Rheumatology, Intensivist.

Global

- The collection of plasma is high.
- Awareness of disease is much high.
- Innovations
- Disease diagnose case is high

INDIAN

- The collection of plasma is low as compare to Global.
- Lack of awareness
- Lack of innovations
- Disease diagnose case is less as compare to global

Thank
you