

ACCESS TO IMMUNOGLOBULIN THERAPIES AN IMPERATIVE FOR PATIENTS

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Keep Life *Flowing*

MANUFACTURING COST STRUCTURES OF PLASMA PROTEIN THERAPIES AND CHEMICAL PHARMACEUTICALS



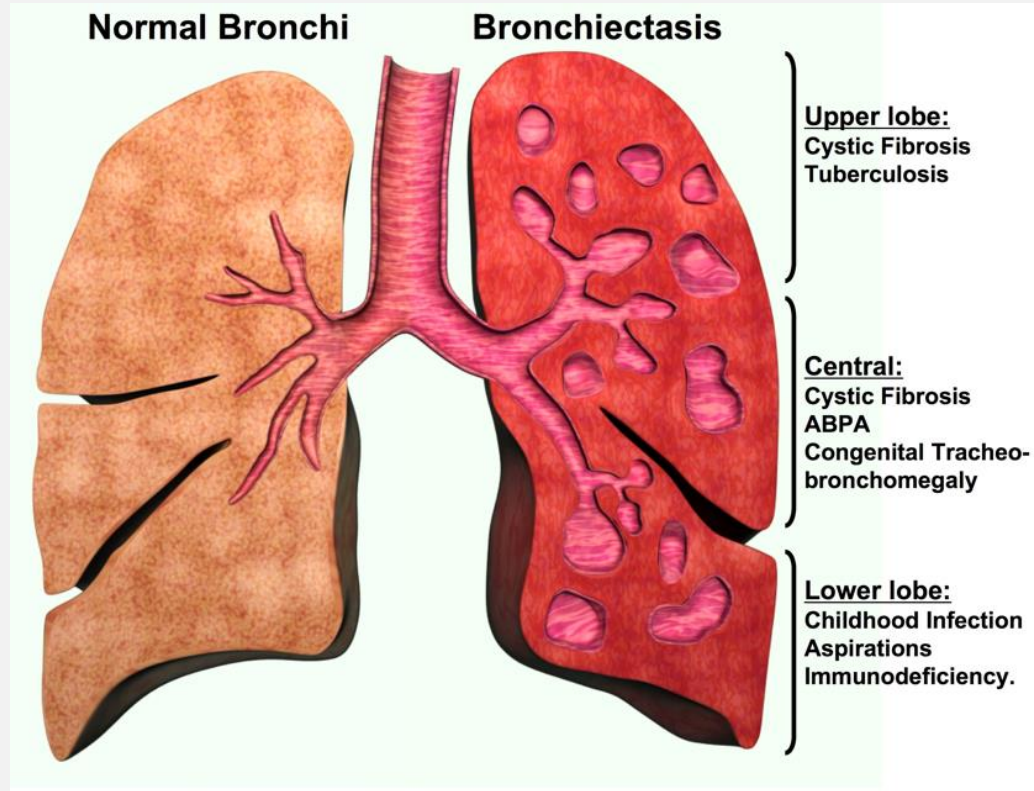
- A class of unique and life-saving medicines
- Current global dependence on US plasma supply
- Importance of national plasma as source of immunoglobulin - local (herd) immunity
- Maximising donor gift by using recovered plasma
- Mandatory to develop plasmapheresis

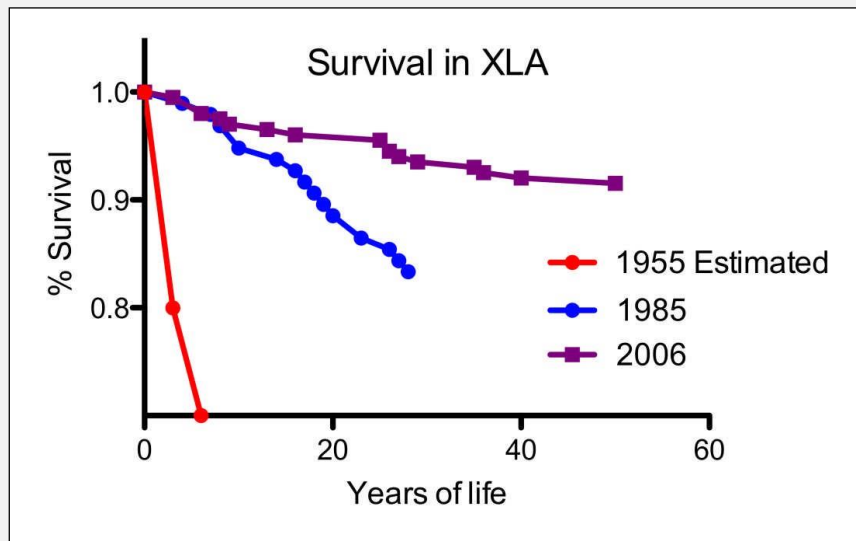
- From an initial possible quantity of **30.000 liters** of plasma available for fractionation there is an outcome of approx.*
 - **4,5 MIU** of FVIII 30% of demand and 10% of needs¹
 - **6 MIU** of Factor IX/PCC 100% of the demand and 40% of needs²
 - **750 kg** of Albumin 70% of demand and 20% of needs³
 - **114 kg** of standard IVIG 80% of demand and 15% of requested quantity⁴

To reach the goal of **1.000 Kg** of Intravenous gamma globulin the amount of plasma to be collected should be around **260.000 liters**, equivalent to approx. **433.000 donations** of 600ml/each....

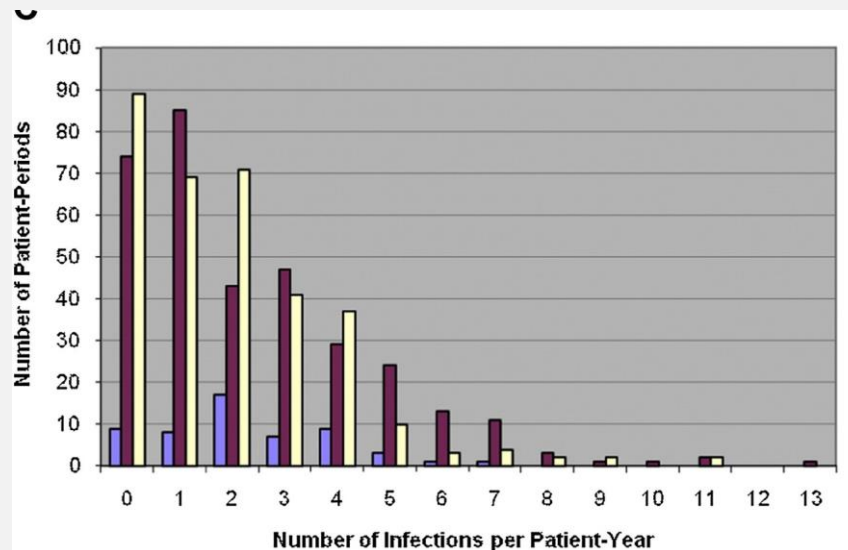
- * The real outcome depends on local requests and quality of plasma
- 1. 2UI/per capita as per WFH Guidelines
- 2. 0,8IU/per capita (average EU consumption WFH annual report)
- 3. 223kg/million ab is the EU average (see MRB report EU data 2014)
- 4. See the target of 1.000Kg set by Romanian MoH

- **260.000 liters** means:
- According to Italian rules (as per MoH Decree 2/11/2015) approx. **21,700** donors with the maximum allowed of 12 liters/year (i.e. 20 donation/year)
- According to German rules : **7.000** donors donating the maximum allowed by law of **38 liters/year** (i.e. 45 donation/year)
- According to Hungarian rules : **11.000** donors donating the maximum allowed by law of **24 liters/year** (i.e. 33 donation/year)





Survival in patients with X-linked agammaglobulinemia (XLA). Increased availability of IgG products increases patient life span. (Source: Presentation by Dr Jordan Orange, PPTA Plasma Forum, June 2010)

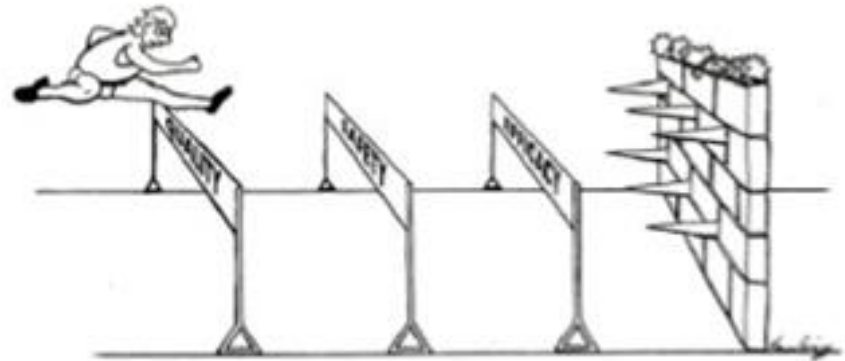


IG therapy over three decades - mean infection number per patient-year for each patient-period across 3 decades. Blue bars, 1980 to 1989; red bars, 1990 to 1999; yellow bars, 2000 to 2007. Each bar represents the number of specific periods in that decade. From Lucas 2010

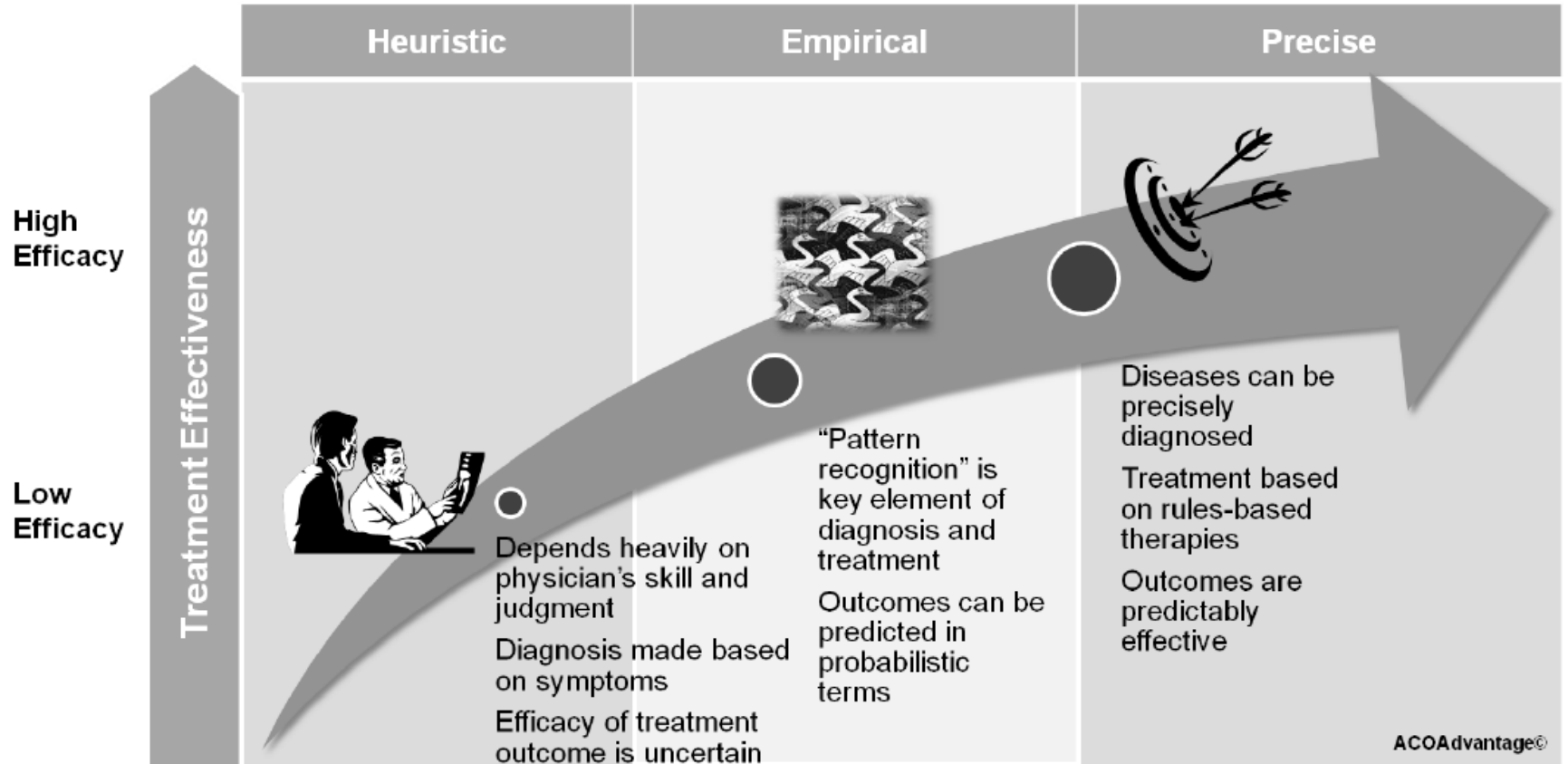


Cost-effectiveness (or CER) has become the "fourth hurdle" to market access

THERE WAS GENERAL AGREEMENT THAT THE FOURTH HURDLE WAS THE ONE TO LOOK OUT FOR

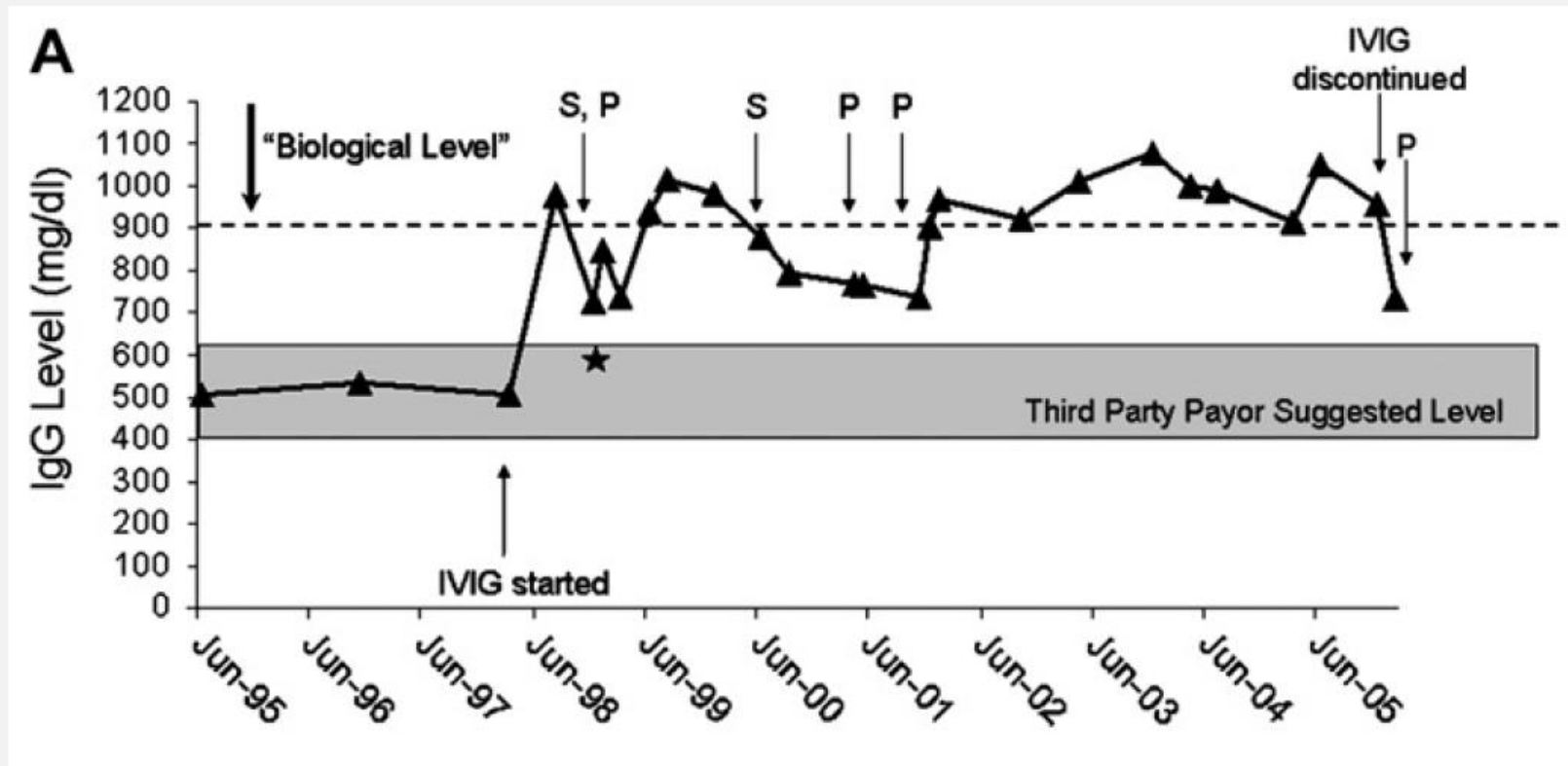


Evolution of Medicine from Heuristic to Precision Based

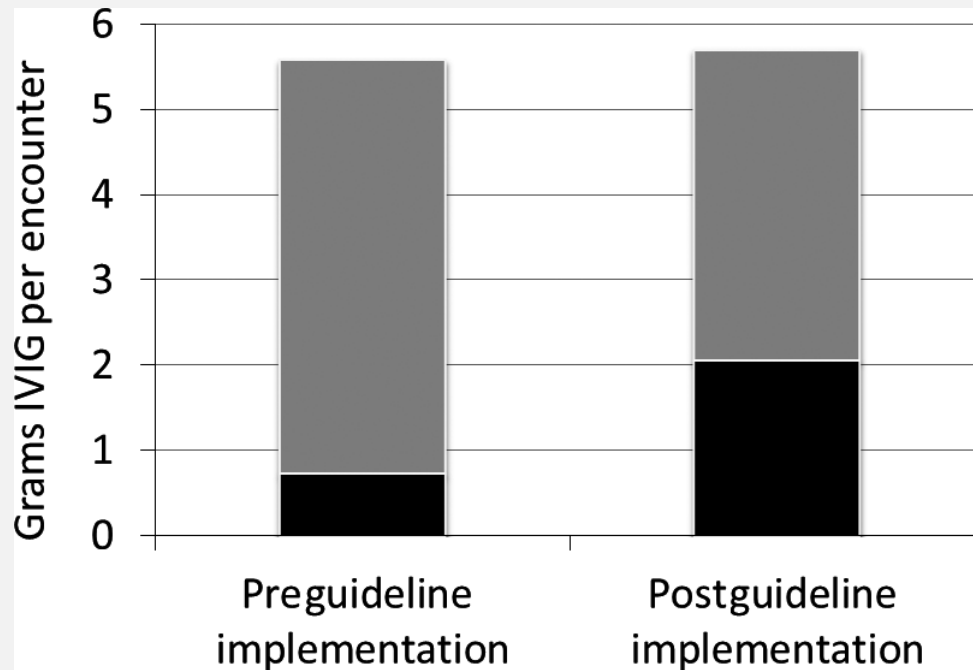
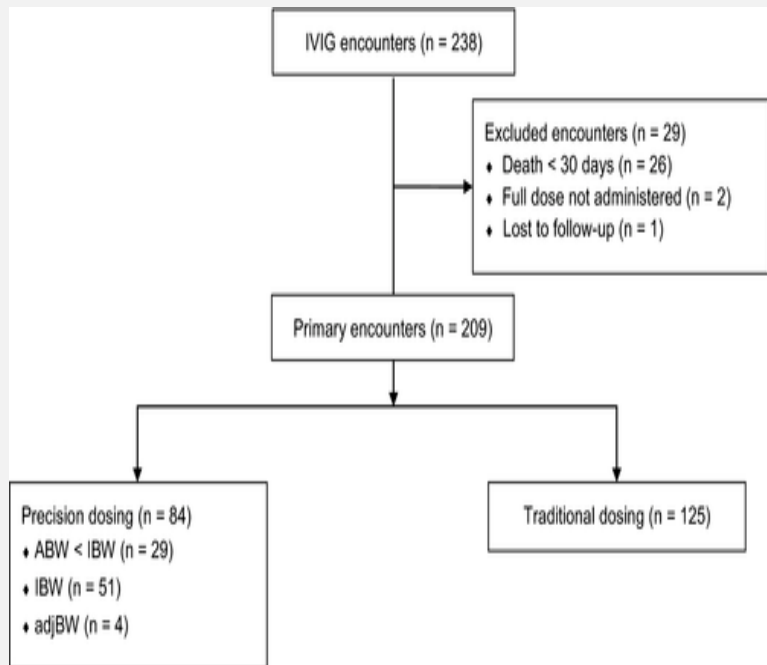


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“PRECISION/PERSONALIZED” TREATMENT FOR PID?



J Allergy Clin Immunol 2008; 122(1):2102



Pharmacotherapy Volume: 37, Issue: 12, Pages: 1530-1536, First published: 13 October 2017, DOI: (10.1002/phar.2047)

POSITIVE AND NEGATIVE IMPACT FACTORS ON HRQOL IN PATIENTS WITH PIDD

Factors negatively impacting quality of life in PIDD patients

Delay in diagnosis

Other chronic health issues

Stress

Unemployment

Repeat infectious episodes

Social factors such as unemployment

Chronic lung disease

Factors positively impacting quality of life in PIDD Patients

Treatment in the home setting

Independence

Convenience of treatment

Comfort of treatment

Less parental impact time

Therapeutic IgG trough levels

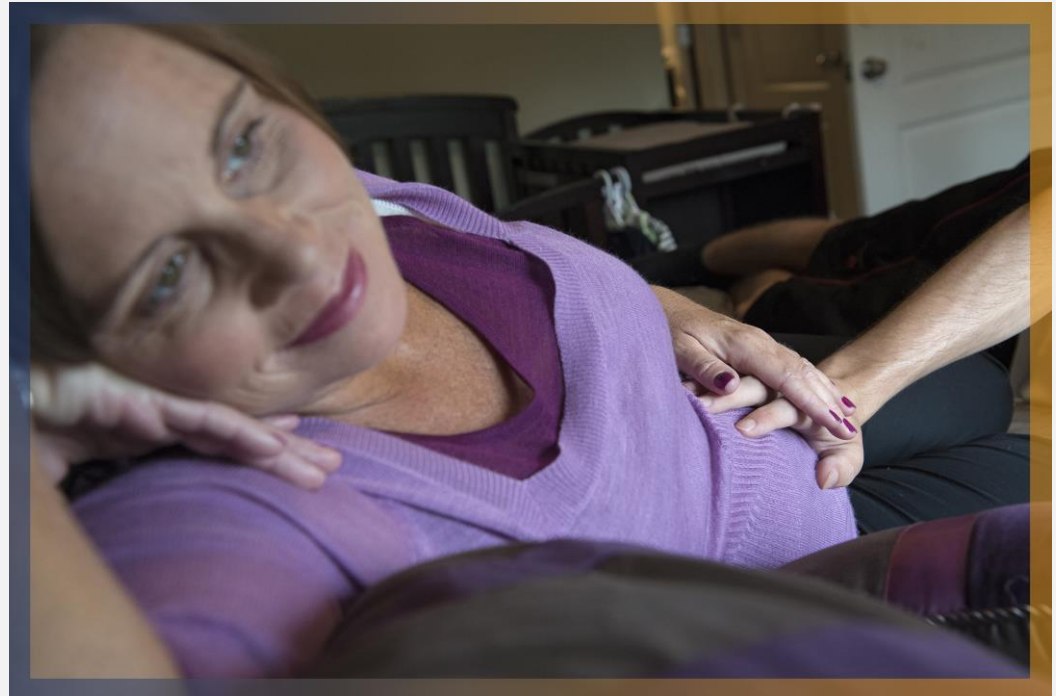
Jiang et al. *Allergy Asthma Clin Immunol* (2015) 11:27

ANOTHER CRUCIAL IMMUNOGLOBULIN

Unbranded educational campaign
supported by Kedrion

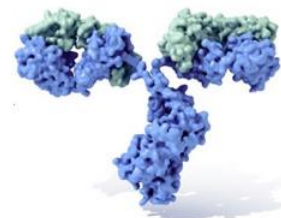


1968-2018
50 YEARS OF ANTI-D





SAFETY AND EFFICACY OF IMMUNOGLOBULIN THERAPIES



A GUIDE FOR USERS, ASSESSORS AND
FUNDERS

ALBERT FARRUGIA



THANKS FOR YOUR ATTENTION

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