



The KPA m2M Group

an introduction

KPA Ltd. 
Management Consulting

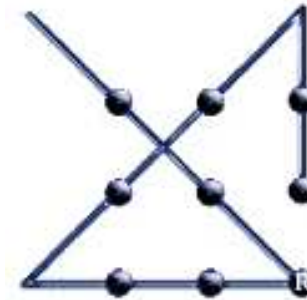
The KPA Group

CREATIVITAS.NET

Creativity taken seriously



Creativitas.net



KPA Ltd.



Univ. of Torino

Crescendo Italia

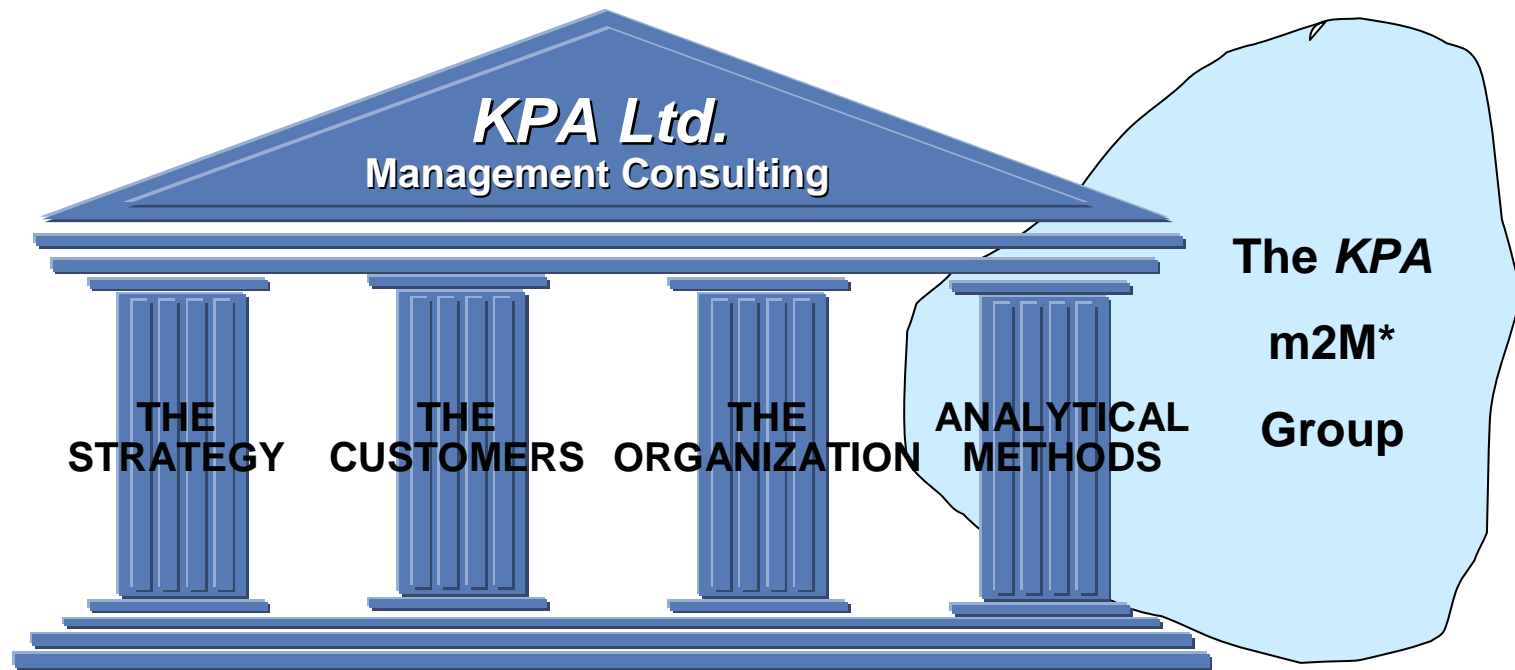
Crescendo Italia



NOVIAS

KPA Ltd.

KPA areas of activity



*m2M: from molecule to Market

***KPA m2M* partial clients' list**

- Perrigo Israel Pharmaceuticals
- ChemAgis
- Teva
- Kamada
- Theravita
- Superdimension
- BTG
- Meditor
- Polyhill
- Savyon Diagnostics
- Foamix
- Interpharm (now Merck Serono)

Research Support for Product Development



5000 to 10000 compounds screened

250 lead candidates

5 drug candidates

80% pass Phase I

30% pass Phase II

80% pass Phase III

1 drug approval by FDA

GLP

Safety

GCP

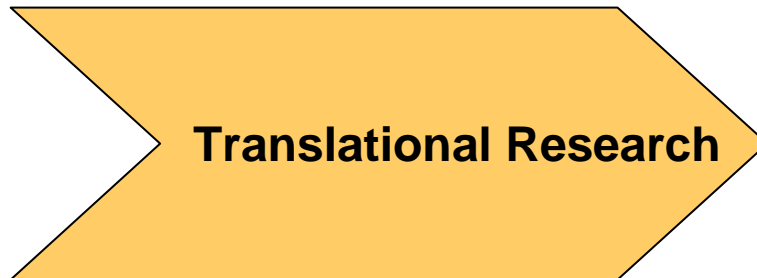
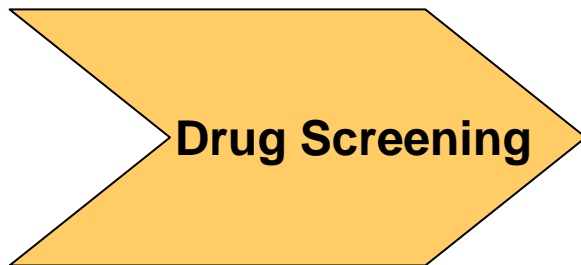
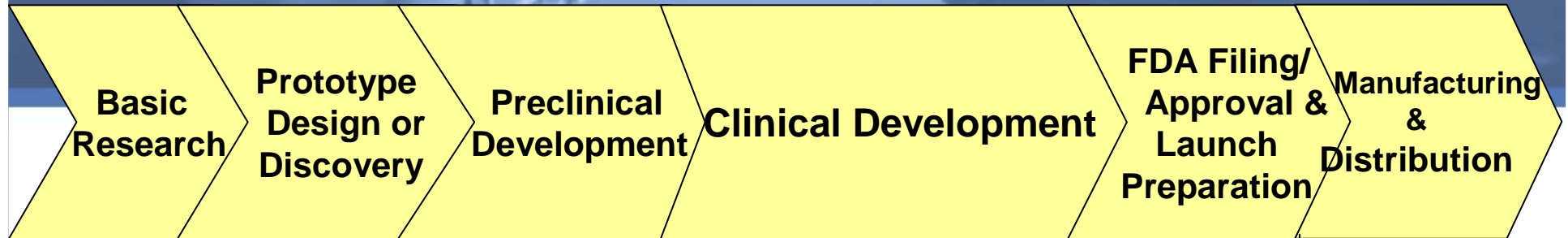
Efficacy

GMP

Quality

GDP

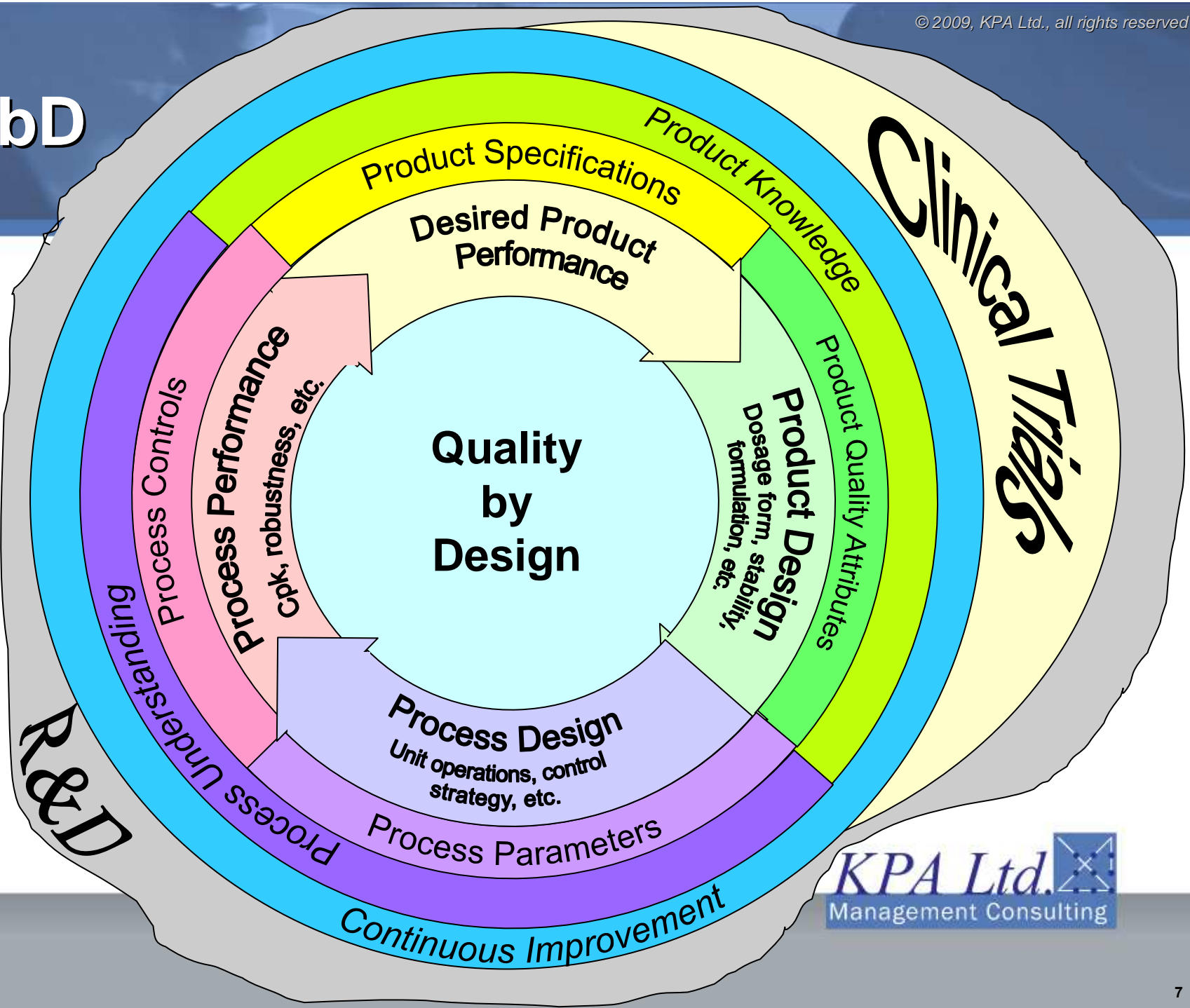
Research Support for Product Development



QbD

Clinical Trials

Q8
Q9
Q10
PAT
...



The m2M Vision

- To be a leading provider of fully integrated solutions to **life sciences enterprises**
- To be recognized as providing **top level quality and cost effective services**
- To be a leading provider of **innovative solutions** on the “**critical path**”.

Our Mission

- To support effective creative development, from the molecule to the market, thus shortening Time to Market and increasing success rate.
- We call our approach **m2M, from molecule to Market.**

Our Strategy

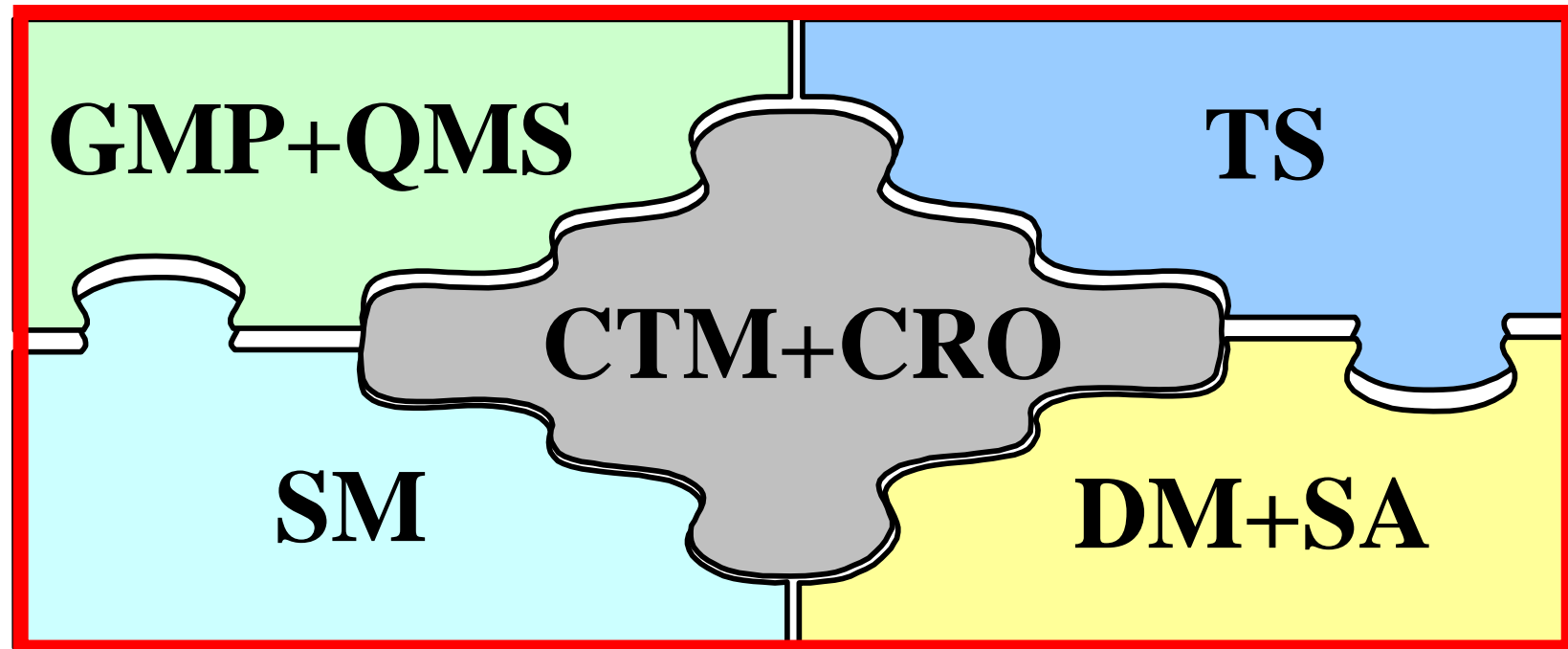
- We provide a creative clinical development strategy
 - using new methodologies and technologies of study design
 - using creative statistics in design and results analyses
- We employ international collaborations, and alliance management
- We also consider option based compensations
- We provide lean and mean thinking to our client organizations

The m2M Puzzle

- **GMP+QMS:** GMP and Quality Management Systems, Regulatory Affairs.
- **SM:** Suppliers Management, drug supplies for clinical studies, Managing Sub -Contractors (central labs etc.....)
- **CTM + CRO:** Clinical Strategy, Clinical Trial Management, Clinical Research Organizations, Drug Safety and Pharmacovigilance, Toxicology, CMC
- **TS:** Training and Certification Systems
- **DM+SA:** Data Management, Statistical Analysis

**An Integrated Approach to
Critical Path Research**

The m2M Puzzle



**An Integrated Approach to
Critical Path Research**

The m2M partners

- Clinical Strategy and Regulatory Affairs - KPA
- Quality Management Systems - KPA
- Risk Management - KPA
- Statistical Analysis - KPA
- Data Management - KPA (DMSys®)
- Toxicology and CMC - SynergyPharma
- Medical Writing - TLR
- CRO - CardioMed

The *KPA* m2M biostatistics group

- Prof Ron Kenett - Biostatistics and Management (KPA and Univ. of Torino)
- Prof David Steinberg - Experimental Design (KPA and Tel Aviv University)
- Dr. Benny Yoskovitch - Biostatistics and Analytical Methods (KPA)
- Dr. Michael Dalith - Pharmacology and Clinical Trials (KPA)
- Nili Bergida - Project and Data Management (KPA)
- Prof Shelley Zacks - Biostatistics and Adaptive Designs (KPA and SUNY)
- Prof Tony Greenfield - Biostatistics and Simulation of Clinical Trials (KPA and Greenfield Research)

Ron S. Kenett - CV

Ron S. Kenett, Ph.D. is CEO and Senior Partner of KPA Ltd., an international management consulting firm and Professor at the University of Torino, Torino, Italy. He has over 25 years of experience in restructuring and improving the competitive position of organizations by integrating statistical methods, process analysis, supporting technologies and modern human resource management systems. As Professor of Management at the State University of New York- Binghamton (1987-1993), he was awarded the General Electric Quality Management Fellowship. For ten years he served as Director of Statistical Methods for Tadiran Telecommunications Corporation and, previously, as researcher at Bell Laboratories in New Jersey and faculty member at the department of Statistics, University of Wisconsin-Madison. His 130 publications are on topics in industrial statistics, biostatistics and quality management. Ron is co-author of four books including - Modern Industrial Statistics: Design and Control of Quality and Reliability (with S. Zacks), Duxbury Press, 1998, Chinese edition, 2004, Multivariate Quality Control: Theory and Applications (with C. Fuchs), Marcel Dekker Inc., 1998 and Software Process Quality: Management and Control (with E. Baker), Marcel Dekker Inc., 1999. Professor Kenett's Ph.D. is in Mathematics from the Weizmann Institute of Science (1978); he earned a BSc. in mathematics with first class honors from Imperial College, London University (1974). Ron is past president of ENBIS, the European Network for Business and Industrial Statistics (www.enbis.org). He can be reached at ron@kpa.co.il.

Ron Kenett - Biostatistics Publications

- Low immunoglobulin A in atopic families. (with C. Geller-Bernstein, N. Keret, A. Bejerano, S. Tsur, L. Weissglass, M. Lahav and M. Sela), *Abst. 15 Meeting Israel Immunol. Soc.*, Tel Aviv, p. 70, 1984.
- "Atopic Babies with Wheezy Bronchitis" (with C. Geller, L. Weissglass, S. Tsur, M. Lahav and S. Levin), *Allergy*, 42, pp. 85-91, 1987.
- "IgA, IgG, IgM, and IgE Levels in Normal, Healthy, Non-atopic Israeli Children" (with C. Geller, T. Barsky, S. Tsur, M. Lahav and S. Levin), *Annals of Allergy*, 61, pp. 296-299, 1988.
- "Aerobiology as a Tool for Prevention of Hay Fever" (with C. Geller-Bernstein, N. Keynan, Shomer-Ilan and Y. Waisel), *Grana*, 30, pp. 76-78, 1991.
- "Aerobiology in the prevention of Allergy" (with C. Geller-Bernstein and Y. Waisel), in **Clinical Applications of Aerobiology**, The UCB Institute of Allergy, Syed Tariq Editor, pp. 69-75, April 1996.
- "Pollen Allergy in Israel" (with C. Geller-Bernstein, G. Hassoun, C. Lahoz, M. Iancovici-Kidon, Y. Waisel), *Pediatric Pulmonology*, Supplement 23:46-47, 2001.
- "Low molecular weight heparin and warfarin in the treatment of patients with Antiphospholipid Syndrome during pregnancy" (with Rachel Pazner, Mordechai Dulitzki, Pnina Langevitz, Avi Livneh, Amira Many), *Tromb. Haemost*, 86, pp. 1379-84, 2001.
- "Is it 'bad hygiene' to inhale pollen in early life?" (with C. Geller-Bernstein, C. Lahoz, B. Cordaba, G. Hassoun, M. Iancovici-Kidon, Y. Waisel), *Allergy*, 57, Suppl. 71, 2002.
- "Does Skin Prick Test Correlate with Basophil-Associated Mite-Specific IgE in Atopic Children?" (with M. Iancovici-Kidon, C. Geller-Bernstein, G. Dwin, A. Licht and I. Pecht), *J. Invest Allergol Clin Immunol*, 13, pp. 73-75, 2003.
- "Hepatic infarctions during pregnancy are associated with the antiphospholipid syndrome and in addition with complete or incomplete HELLP syndrome" (with R. Pazner, M. Dulitzki, H. Carp, H. Mayan, Z. Farfel and A. Many), *Journal of Trombosis and Haemostasis*, 1, pp. 1758-1763, 2003.
- "Allergies in immigrants" (with C. Geller), *European Journal of Allergy and Clin. Immunol*, 36, 8, pp. 313-316, 2004.
- "The Relationship Between HLA Antigens and Bermuda Grass Hayfever" (with C. Geller, R. Zamir, S. Karlin and M. Sela), *Immunogenetics*, 7, pp. 259-264, 1978.
- "Genetic Markers: Benign and Normal Traits of the Ashkenazi Population in Israel" (with B. Bonne and S. Ashbel) in **Genetic Diseases in Ashkenazi Jews**, eds.: R. Goodman and A. Motulsky, Raven Press, New York, pp. 59-76, 1979.
- "Analysis of Biochemical Genetic Data on Jewish Populations: I. Historical Background, Demographic Features and Genetic Markers" (with S. Karlin and B. Bonne), *American Journal of Human Genetics*, 31, pp. 324-340, 1979.
- "Analysis of Biochemical Genetic Data on Jewish Populations: II. Results and Interpretations Heterogeneity Indices and Distance Measures with Respect to Standards" (with S. Karlin and B. Bonne), *American Journal of Human Genetics*, 31, pp. 341-365, 1979.
- "Bioassay of Kinship in Populations of Middle Eastern Origin" (with N. Morton, S. Yee and R. Lew), *Current Anthropology*, 23, pp. 157-167, 1982.
- Heritability of IgA levels in atopic families. C. Geller-Bernstein, R. Kenett, S. Tsur, L. Weissglas, A. Bejerano, M. Lahav and M. Sela, *Abstr. XII Cong. Eur. Acad. Allerg. Clin. Imm.*, Rome, Sept. 25-30, 1983, *Folia Allergologica et Immunologica Clinica*, 30, Suppl. 4, 105 1983.
- "Survey of Immunoglobulin Levels in Atopic Families" (with C. Geller, N. Keret, A. Bejerano, B. Reisman, S. Tsur and Michael Sela), *Asian Pacific Journal of Allergy and Immunology*, 2, pp. 181-185, 1984.
- "Survey of Immunoglobulin E Levels in Atopic Families in Israel" (with C. Geller, L. Weissglass, N. Keret, R. Dun, A. Bejerano, M. Lahav and Michael Sela), *Israel Journal of Medical Science*, 20, pp. 1133-1137, 1984.



**Thank you for
your attention**