Quality Assessment and Standardization
2019 - 2020
Subcommittees under QAS Committee

• Allergen Standardization - Stefan Vieths – Germany

• Autoantibodies in Rheumatic and Related Diseases – Edward Chan - USA

• Complement – Michael Kirschfink – Germany

• Leukocytes – Pablo Engel – Spain

• Big Data in Immunology – Jamie Scott - USA
QAS Goals & Objectives

• Promote quality assessment and standardization in the various areas of immunology

• Build a sense of belonging towards IUIS

• Promote exchange of experience among subcommittees
QAS Committee proposals and aims

• Expand the spectrum of immunology areas covered by QAS

• Promote gender and geographical balance

• Stimulate independent fund raising linked to specific projects

• Contribute short communications to IUIS Newsletter & Website

• Contribute Research Topic to Frontiers in Immunology

• Promote seminars/workshops on IUIS annual events
  • International Congress of Immunology
  • American College of Rheumatology
  • International Complement Society
• Expand the spectrum of immunology areas to be covered by QAS

  • Immunologic diagnosis of infectious diseases
  • Immunological diagnosis of immunodeficiencies
  • Cytokine determination
  • Autoantibodies in neurologic autoimmune diseases
  • Autoantibodies in liver autoimmune diseases
  • Autoantibodies in skin autoimmune diseases
  • HLA determination
Subcommittees under QAS Committee

- Allergen Standardization - Stefan Vieths – Germany
- Autoantibodies in Rheumatic and Related Diseases – Edward Chan - USA
- Complement – Michael Kirschfink – Germany
- Leukocytes – Pablo Engel – Spain
Current trends in QAS Committee

Subcommittees under QAS Committee

• Allergen Standardization - Stefan Vieths – Germany
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Current trends in QAS Committee

Subcommittees under QAS Committee

- Allergen Standardization - Stefan Vieths – Germany
- Autoantibodies in Neurologic Diseases – Romana Höftenberg (University of Vienna) ➔ accepted preliminarily and is currently in the process of organizing the subcommittee
- Autoantibodies in Rheumatic and Related Diseases – Edward Chan - USA
- Big Data in Immunology – Jamie Scott - USA
- Cytokines – Menu Wadha (NIBSC - London) ➔ accepted and contributed one article to the IUIS Newsletter
- Complement – Michael Kirschfink – Germany
- Leukocytes – Pablo Engel – Spain
- Serology in Infectious Diseases - Syria Laperche (Institut Hemotransfusion - Paris) ➔ accepted preliminarily and is currently in the process of organizing the subcommittee
Gender balance in QAS subcommittees

- Allergen Standardization – 2F & 14M ➔ 4F & 12 M
- Autoantibodies in Rheumatic and Related Diseases – 0F & 20 M ➔ 4F & 20 M
- Bid Data in Immunology - 6F & 9 M
- Complement – 1F & 16 M ➔ 14F & 8 M
- Leukocytes – 3F & 6 M
Research Topic in Frontiers in Immunology

Contemporary Challenges in Immunologic Testing in Clinical and Research Laboratories

• Topic Editor: Luis Andrade
• Associate Editors: Edward Chan, Pablo Engel, Michael Kirschfink, Stefan Vieths
• Deadline for manuscript submission: March 31, 2021
• 29 contributors invited:
  • 16 confirmed
  • 12 not replied
  • 1 declined
• Four manuscripts submitted
• Three more abstracts submitted
Independent fund raising linked to specific projects

• ASC ➔ International Consensus on ANA Patterns (ICAP)

  • Initiative of the Autoantibody Standardization Committee
  
  • Website (www.anapatterns.org) ➔ over 3,000 subscribed members, over 174,292 visits in the last 12 months, 156 countries, translation into 14 languages

  • Self funding using unrestricted educational grants from private industries in the area of diagnosis ➔ Aesku, Biorad, Byosystems, Euroimmun, Grifols, Immunoconcepts, Inova, Medical & Biological Laboratory, Mitogen, Thermo Fisher, Trinity Biotech) ➔ US$ 25,000
Welcome to ANApatterns.org, the official website for the International Consensus on Antinuclear Antibody (ANA) Patterns (ICAP). ICAP was initiated as a workshop aiming to thoroughly discuss and to promote consensus regarding the richness in nuances of morphological patterns observed in the indirect immunofluorescence assay on HEP-2 cells. The ICAP initiative was implemented at the 12th International Workshop on Autoantibodies and Autoimmunity (IWAA) by members of the Autoantibody Standardization Committee (ASC), a subcommittee of the International Union of Immunological Societies (IUIS) Quality Assessment and Standardization Committee and affiliated with the Centers for Diseases Control and Prevention (CDC). The ICAP committee is operating as an ASC sub-committee.
Development of the ANApatterns.org website

Number of website users by year

- 2015: 5710
- 2016: 15951
- 2017: 35995
- 2018: 50249
ANApatterns.org visited in 156 countries

Source: Google Analytics date from August 2018 to August 2019.
# Top 20 countries accessing ANApatterns.org

<table>
<thead>
<tr>
<th>Country</th>
<th>Website Users</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>20,040 (22.18%)</td>
</tr>
<tr>
<td>Spain</td>
<td>4,567 (5.05%)</td>
</tr>
<tr>
<td>Germany</td>
<td>3,969 (4.39%)</td>
</tr>
<tr>
<td>Chile</td>
<td>3,876 (4.29%)</td>
</tr>
<tr>
<td>India</td>
<td>3,709 (4.10%)</td>
</tr>
<tr>
<td>Brazil</td>
<td>3,386 (3.75%)</td>
</tr>
<tr>
<td>Italy</td>
<td>3,295 (3.65%)</td>
</tr>
<tr>
<td>Mexico</td>
<td>3,158 (3.49%)</td>
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<tr>
<td>Switzerland</td>
<td>2,777 (3.07%)</td>
</tr>
<tr>
<td>Argentina</td>
<td>2,559 (2.83%)</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>Country</th>
<th>Website Users</th>
</tr>
</thead>
<tbody>
<tr>
<td>Taiwan</td>
<td>2,083 (2.30%)</td>
</tr>
<tr>
<td>South Korea</td>
<td>1,985 (2.20%)</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>1,972 (2.18%)</td>
</tr>
<tr>
<td>Portugal</td>
<td>1,761 (1.95%)</td>
</tr>
<tr>
<td>Belgium</td>
<td>1,725 (1.91%)</td>
</tr>
<tr>
<td>China</td>
<td>1,576 (1.74%)</td>
</tr>
<tr>
<td>Colombia</td>
<td>1,569 (1.74%)</td>
</tr>
<tr>
<td>Canada</td>
<td>1,525 (1.69%)</td>
</tr>
<tr>
<td>Austria</td>
<td>1,472 (1.63%)</td>
</tr>
<tr>
<td>Netherlands</td>
<td>1,465 (1.62%)</td>
</tr>
</tbody>
</table>
ANApatterns.org - usage demographics

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-24</td>
<td>11.3%</td>
</tr>
<tr>
<td>25-34</td>
<td>36.8%</td>
</tr>
<tr>
<td>35-44</td>
<td>22.7%</td>
</tr>
<tr>
<td>45-54</td>
<td>13.9%</td>
</tr>
<tr>
<td>55-64</td>
<td>10%</td>
</tr>
<tr>
<td>65+</td>
<td>5.3%</td>
</tr>
</tbody>
</table>

Gender Distribution:
- Male: 38.5%
- Female: 61.5%
## Download Files

<table>
<thead>
<tr>
<th>Preview</th>
<th>File / Description</th>
<th>Download / Size</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="https://www.anapattems.org" alt="Preview" /></td>
<td><strong>ICAP presentation file</strong>&lt;br&gt;Powerpoint presentation with the individual classification trees and two representative AC patterns</td>
<td><img src="https://www.anapattems.org" alt="Download" /> (9.7 MB)</td>
</tr>
<tr>
<td><img src="https://www.anapattems.org" alt="Preview" /></td>
<td><strong>ICAP Page 1</strong>&lt;br&gt;Page with nomenclature, classification tree and patterns informations (synonyms, antigen and disease associations). Recommended for printing on A4/Letter compatible paper.</td>
<td><img src="https://www.anapattems.org" alt="Download" /> A4 (254.83 KB)</td>
</tr>
<tr>
<td><img src="https://www.anapattems.org" alt="Preview" /></td>
<td><strong>ICAP Page 2</strong>&lt;br&gt;Page with representative images of each pattern (AC-1 to 26). Recommended for printing on A4/Letter compatible paper.</td>
<td><img src="https://www.anapattems.org" alt="Download" /> A4 (2.81 MB)</td>
</tr>
<tr>
<td><img src="https://www.anapattems.org" alt="Preview" /></td>
<td><strong>ICAP Page 3</strong>&lt;br&gt;Informative page with nomenclature, classification tree and representative image of each pattern (AC-1 to 28). Recommended for printing on A4/Letter compatible paper.</td>
<td><img src="https://www.anapattems.org" alt="Download" /> A4 (5.30 MB)</td>
</tr>
<tr>
<td><img src="https://www.anapattems.org" alt="Preview" /></td>
<td><strong>ICAP Poster 4</strong>&lt;br&gt;Poster with nomenclature, classification tree and patterns informations (synonyms, antigen and disease associations)</td>
<td><img src="https://www.anapattems.org" alt="Download" /> Letter (20.6 MB)</td>
</tr>
</tbody>
</table>
Sponsors

- Grifols
- Immuno Concepts
- Bio-Rad
- BioSystems
- Trinity Biotech
- Mitogen Dx
- Medical & Biological Laboratories Co., Ltd.
Independent fund raising linked to specific projects

- Leukocyte Committee
  - Sponsorship for the HCDM webpage: 6,000 Euros
  - Biolegend (20,000 Euros)
  - Thermo Fisher (5,000 Euros)
- Sponsors of HLDA11 and CDMaps (providing monoclonal antibodies for a total value of more than 100,000 Euros, especially Biolegend, ExBio and Bio-techne (R&D)
Independent fund raising linked to specific projects

• Allergen Standardization Subcommittee

• Funding of the BSP09 Project on development of allergen reference materials by the European Directorate for the Quality of Medicines and Health Care (EDQM)
Independent fund raising linked to specific projects

- Complement Committee
  - Funding for educational grants and QA-related activities from private industries in the area of diagnosis – initiated 2019 via ICS-industry contracts
  - Planned activity with the International Complement Society (ICS) – industry workshop in the occasion of the International Complement Workshop (Berlin), being postponed to 2021
Activities of the QAS Committee since the last Council Meeting
Big Data in Immunology

QAS 2020 Activities

• Approval of the proposal of the subcommittee by IUIS Council on June, 2020

• Leadership
  • Jamie Scott (Chair) - Simon Fraser University, Burnaby, Canada
  • Felix Bredan (Vice-chair) - Simon Fraser University, Burnaby, Canada

• Mission and values
  • Standardization and/or interoperability of existing and newly generated “BDI” following FAIR principles and utilizing currently accepted ontologies where available;
  • Free and public availability of data and associated metadata following FAIR principles; and
  • Development of open-source and freely available tools, pipelines and repositories following FAIR principles
Big Data in Immunology

QAS 2020 Activities

Definition of goals

• Surveying IUIS member societies and other relevant entities for their interest in, concerns about, and priorities for BDI and their standardization.
• Creating, integrating with, and/or promoting Working Groups involved in standardization of different types of BDI and their analysis, storage, sharing;
• Supporting training in BDI-related topics, especially in low-to-middle income countries
• Collaborating/integrating with other entities that share the same objectives (e.g., goFAIR?, and the Research Data Alliance (RDA);
• Partnering with IUIS societies, governments, international agencies, and other entities to educate and promote BDI standards; and
• Developing recommendations on policies for universal standards to be implemented by national and international agencies, including funding agencies and journals.
Big Data in Immunology

Members

• Bjoern Peters, La Jolla Institute for Immunology, USA
• Adrian Thorogood, The Global Alliance for Genomics & Health, Montreal, Canada
• Peter Goodhand, The Global Alliance for Genomics & Health, Montreal, Canada
• Rose Gana Fomban Leke, Human Heredity & Health (H3) Africa Network
• Christian Busse, German Cancer Research Center, Heidelberg, Germany
• Fiona Brinkman, Simon Fraser University, Burnaby, BC, Canada
• Lynn Morris, National Institute for Communicable Disease, Johannesburg, South Africa
• Penny Moore, National Institute for Communicable Disease, Johannesburg, South Africa
• Catherine Scheepers, National Inst for Communicable Disease, Johannesburg, South Africa
• Steven Quake, Chan-Zuckerberg Biohub, San Francisco, USA
• Helder Nakaya, Systems immunology Department, San Paulo University, Brazil
• Hiroyuki Kishi, T-cell receptor repertoires Discipline, University of Toyama, Japan
• Xiao Liu, Beijing Genomics Institute, Shenzhen, China
Big Data in Immunology

QAS 2020 Activities

AIRR Community Special Event

Leveraging AIRR-sequencing data to inform the biology of COVID-19

On-line (Zoom) international meeting - September 8-10
Allergen Standardization

QAS 2019-2020 Activities

• Standards for recombinant major allergens Phl p 5 (*timothy grass* pollen) and Bet v 1 (birch pollen) have been successfully validated in collaboration with the European Directorate for the Quality of Medicines (EDQM)

• ELISA methods have been validated internationally and are commercially available

• Project BSP163 was initiated under the auspices of the EDQM to prepare a second batch of the two respective standards to meet the increasing need

• Next meeting of IUIS Allergen Standardization Subcommittee ➔ 2020 Paul-Ehrlich-Seminar will occur in early December in virtual format
Autoantibody Standardization in Rheumatic Diseases

QAS 2019/2020 Activities

- Four new Reference Material Standards
  - Anti-Sp100 (AC-6 ICAP pattern)
  - Anti-NuMA/Centrofilin antibody (AC-26 ICAP pattern)
  - Anti-GW body (cytoplasmic P bodies) (AC-18 ICAP pattern)
  - Anti-DFS70 (AC-2 ICAP pattern)
- Two publications in the journal Clin. Chem. Lab. Med, with detailed characterization of these reference materials
- ICAP mini-workshop at the Shenzhen Rheumatology Meeting, Shenzhen, China, October 25, 2019
- IUIS Autoantibody Standardization Subcommittee Annual Study Group “Autoantibodies in Diagnosis and Follow up of Rheumatic Diseases”, Atlanta, November 11, 2019
- Planned ICAP mini-workshops at PANLAR Congress in Miami, May 2020 and 12th International Congress on Autoimmunity, Athens, Greece, May 2020 ➔ postponed to May 2021
Establishment of a new website (www.ANApatterns.cn) as a mirror site to allow for efficient access of web-based content in China – organized by Dr. Bing Zheng, in Shanghai

New translation of ICAP website are in various developing stages, including Thai and Romanian

First planned ICAP training module was completed and made available online in July 2020 ➔ certificate provided after full completion of the module ➔ participants from over 60 countries!

Training modules #2, 3, and 4 are under construction

UIUS Autoantibody Standardization Subcommittee Annual Study Group session “Autoantibodies in Diagnosis and Follow up of Rheumatic Diseases”, Atlanta, November 11, 2019

ICAP WORKSHOP at PANLAR Congress (VIRTUAL CONGRESS), 17-20 September, 2020

Planned ICAP WORKSHOP at the 12th International Congress on Autoimmunity, Athens, May 2021
Autoantibody Standardization in Rheumatic Diseases

Publications 2019/2020


• Setting up *Guidelines for the Diagnosis and Management of Complement Deficiencies* in cooperation with the European Society of Immunodeficiencies (ESID)

• External Quality Assessment of Diagnostic Complement
  - Round 12: October 2019 (EQA12) ➔ 180 participating labs (20 parameters worldwide, new countries)
  - Round 13: March 2020 (EQA13) ➔ 172 participating labs (11 parameters, worldwide)
  - Round 14: October 2019 (EQA14) ➔ 207 participating labs (20 parameters, worldwide)

• 13th Complement EQA Meeting (European Complement Congress, Madrid, September, 2019)
• 14th Complement EQA Meeting (European Complement Congress, Berlin, September, 2020) postponed to September 2021
Educational actions

Online-Meeting of the Working Group Complement German Society of Immunology

(Presentation: Clinic and Diagnostics of Complement Deficiencies)

Leukocyte Subcommittee

QAS 2019/2020 Activities

• CD Maps Project ➔ aims to define the expression patterns of all established CD molecules using 12 color-flow cytometry
  • Quantitative determination of the expression of cell markers in leukocyte and lymphocyte 44 subsets of the blood, tonsil and thymus
  • Data base corresponding to CD1 to CD100 is complete and is open to the public at www.hcdm.org (http://bioinformin.cesnet.cz/CDmaps/).
  • Second phase of the project to complete the analysis of CD101 to CD371 expression
  • The HCDM/HLDA web www.hcdm.org. has been improved. The contribution of the IUIS is acknowledged at the web page.
• Programming the HLDA11 Workshop

  • To be focused on Seven-span receptors and ion channels
  • Aim to create a panel of antibodies of more than 200 mAbs
  • mAbs under testing using 12-color flow cytometry
  • Ascribe CD nomenclature to the newly validated monoclonal antibodies
  • We foresee that we will able to define a minimum of 20 new CDs
  • HLDA11 protocol can be found at
Educational actions


• Lecture on “Antibody validation for flow cytometry” by Pablo Engel at the meeting “Enabling scientific reproducibility with antibodies: Validation, standards, technology”, June 1st, 2020
Challenges and opportunities for the future
QAS Challenges

- Private industry: exuberant and independent development of reagents, diagnostic kits, arbitrary units, instruments and processes
- Independent coexisting units and cut-off values for the same analyte → opportunity for building international standards
- Shortage of international standards → much work to be done!
- Disconnection of end-users (physicians and researchers) regarding technical nuances of immunologic tests → opportunity in educational activity
QAS Opportunities

• Integration and mutual collaboration among QAS subcommittees

• Identify possibilities of synergy comprehending ≥ 2 subcommittees

• Interaction with industry seeking standardization
  • Collaborative initiatives
  • Fund raising

• Educational and publicizing initiatives regarding the need for standardization and quality assessment