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

• Organ-Specific Autoantibodies - Alberto Falorni – Italy
QAS Goals & Objectives

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

• Build a sense of belonging towards IUlS

• 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 regular virtual meetings among subcommittees
- Promote seminars/workshops on IUIS annual events (e.g., ICI, ACR, Complement Society)
QAS Committee proposals and aims

• Expand the spectrum of immunology areas 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
Current trends in QAS Committee

Subcommittees under QAS Committee

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  - Autoantibodies in neurologic diseases – Romana Höftenberg (University of Vienna)
  - Serology in infectious diseases - Syria Laperche (Institut Hemotransfusion - Paris)
- Cytokines – Menu Wadha (NIBSC - London)
Quality Assessment and Standardization (QAS)

Current trends in QAS Committee

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Gender balance in QAS subcommittees

- Allergen Standardization – 2F & 14M → 4F & 12 M
- Autoantibodies in Rheumatic and Related Diseases – 0F & 20 M → 4F & 20 M
- Complement – 1F & 16 M → 14F & 8 M
- Leukocytes – 3F & 6 M
Independent fund raising linked to specific projects

- ASC ➔ International Consensus on ANA Patterns (ICAP)
  - Initiative of the Autoantibody Standardization Committee
  - Website (www.anapatterns.org) ➔ 2,900 subscribed members, over 100,000 visits, 156 countries, translation into 12 languages
  - Self funding using unrestricted educational grants from private industries in the area of diagnosis ➔ Aesku, Biorad, Euroimmun, Grifols, Inova, Medical & Biological Laboratory, 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
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>
<th>Users (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>20,040</td>
<td>(22.18%)</td>
</tr>
<tr>
<td>Spain</td>
<td>4,567</td>
<td>(5.05%)</td>
</tr>
<tr>
<td>Germany</td>
<td>3,969</td>
<td>(4.39%)</td>
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<tr>
<td>Chile</td>
<td>3,876</td>
<td>(4.29%)</td>
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<tr>
<td>India</td>
<td>3,709</td>
<td>(4.10%)</td>
</tr>
<tr>
<td>Brazil</td>
<td>3,386</td>
<td>(3.75%)</td>
</tr>
<tr>
<td>Italy</td>
<td>3,295</td>
<td>(3.65%)</td>
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<tr>
<td>Mexico</td>
<td>3,158</td>
<td>(3.49%)</td>
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<tr>
<td>Switzerland</td>
<td>2,777</td>
<td>(3.07%)</td>
</tr>
<tr>
<td>Argentina</td>
<td>2,559</td>
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<tr>
<td>Taiwan</td>
<td>2,083</td>
<td>(2.30%)</td>
</tr>
<tr>
<td>South Korea</td>
<td>1,985</td>
<td>(2.20%)</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>1,972</td>
<td>(2.18%)</td>
</tr>
<tr>
<td>Portugal</td>
<td>1,761</td>
<td>(1.95%)</td>
</tr>
<tr>
<td>Belgium</td>
<td>1,725</td>
<td>(1.91%)</td>
</tr>
<tr>
<td>China</td>
<td>1,576</td>
<td>(1.74%)</td>
</tr>
<tr>
<td>Colombia</td>
<td>1,569</td>
<td>(1.74%)</td>
</tr>
<tr>
<td>Canada</td>
<td>1,525</td>
<td>(1.69%)</td>
</tr>
<tr>
<td>Austria</td>
<td>1,472</td>
<td>(1.63%)</td>
</tr>
<tr>
<td>Netherlands</td>
<td>1,465</td>
<td>(1.62%)</td>
</tr>
</tbody>
</table>
ANApatterns.org - usage demographics

Gender distribution: 38.5% Male, 61.5% Female

Age distribution:
- 18-24: 11.3%
- 25-34: 36.8%
- 35-44: 22.7%
- 45-54: 13.9%
- 55-64: 10%
- 65+: 5.3%
## Download Files

<table>
<thead>
<tr>
<th>Preview</th>
<th>File / Description</th>
<th>Download / Size</th>
</tr>
</thead>
</table>
| ![ICAP presentation file](https://www.anapattems.org/download_files.php) | ICAP presentation file  
Powerpoint presentation with the individual classification trees and two representative AC patterns | ![Download](https://www.anapattems.org/download_files.php) (37.7 MB) |
| ![ICAP Page 1](https://www.anapattems.org/download_files.php) | ICAP Page 1  
Page with nomenclature, classification tree and patterns informations (synonyms, antigen and disease associations). Recommended for printing on A4/Letter compatible paper. | ![Download](https://www.anapattems.org/download_files.php) (1.8 MB) |
| ![ICAP Page 2](https://www.anapattems.org/download_files.php) | ICAP Page 2  
Page with representative images of each pattern (AC-1 to 26). Recommended for printing on A4/Letter compatible paper. | ![Download](https://www.anapattems.org/download_files.php) (2.8 MB) |
| ![ICAP Page 3](https://www.anapattems.org/download_files.php) | ICAP Page 3  
Informative page with nomenclature, classification tree and representative image of each pattern (AC-1 to 28). Recommended for printing on A4/Letter compatible paper. | ![Download](https://www.anapattems.org/download_files.php) (4.3 MB) |
| ![ICAP Poster 4](https://www.anapattems.org/download_files.php) | ICAP Poster 4  
Poster with nomenclature, classification tree and patterns informations (synonyms, antigene and disease associations). Recommended for printing on A4/Letter compatible paper. | ![Download](https://www.anapattems.org/download_files.php) (5.3 MB) |
Unrestricted Educational Grant Support for the Autoantibody Standardization Committee – ASC/ICAP
Independent fund raising linked to specific projects

• Leukocyte Committee

  • Sponsorship for the HCDM webpage: 6,000 Euros
    • Biolegend
    • Thermo Fisher
  • Sponsors of HLDA11 and CDMaps (providing monoclonal antibodies for a total value of approx. 50,000 Euros)
  • BD / Biolegend / ExBio / 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
Activities of the QAS Committee since the last Council Meeting
Allergen Standardization

QAS 2018-2019 Activities

- Next meeting of IUIS Allergen Standardization Subcommittee ➔ 2020 Paul-Ehrlich-Seminar

- Ongoing project: development of recombinant allergen standards and ELISA methods for allergen quantification (in collaboration with the European Directorate for the Quality of Medicines)

- EDQM Ring Trial on the quantification of the major allergen Phl p 5 in *timothy grass* pollen extract completed in 2018. Report and publication in progress.

- Collaboration with IUIS Allergen Nomenclature Subcommittee

- Recent publication: Bet v 1 (BSP 090) Overview on the activities of the IUIS Allergen Subcommittee. Molecular Immunology 2018; doi 10.1016/j.molimm.2018.03.003
Autoantibody Standardization in Rheumatic Diseases

QAS 2019 Activities

• 4\textsuperscript{rd} International Autoantibody Standardization workshop, Dresden, September 9, 2019

• 5\textsuperscript{th} International Consensus on ANA Patterns (ICAP) workshop, Dresden, September 9, 2019

• ICAP mini-workshop at the Annual Scientific Meeting of the Korean Society of Laboratory Medicine, Busan, South Korea, September 26, 2019

• 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 12\textsuperscript{th} International Congress on Autoimmunity Athens, Greece, May 2020
Autoantibody Standardization in Rheumatic Diseases

QAS 2019 Activities

• Implementation of three novel international reference materials
  • Anti-mitochondria (PDC-E2 fraction) antibody (AC-21 ICAP pattern)
  • Anti-inosine monophosphate dehydrogenase (AC-23 ICAP pattern)
  • Anti-DFS70/LEDGFp75 antibody (AC-2 ICAP pattern) – Megapool project
• Three novel international reference materials under preparation
  • Anti-Sp100 (AC-6 ICAP pattern)
  • Anti-NuMA/Centrofilin antibody (AC-26 ICAP pattern)
  • Anti-GW body (cytoplasmic P bodies) (AC-18 ICAP pattern)
Autoantibody Standardization in Rheumatic Diseases

QAS 2018 Educational Activities

- International Consensus on ANA Patterns (ICAP) Course during the 11th International Congress of Autoimmunity, Lisbon, Portugal, May 17, 2018
- ANA Workshop entitled “ANA IFA: a workshop for laboratory leaders” during the Congress of the American Association of Clinical Chemistry (AACC), Chicago, USA, July 29, 2018
- Short Courses entitled “Developing Standards in ANA IFA Interpretation and Reporting” during the AACC congress, Chicago, USA, July 30, 2018
- ICAP Practical Course (6 hours) during the Autoantibodies and Detection Guidelines and Advanced Training Course on Autoantibody Detection, Shenzhen, China, October 12, 2018
- IUIS Autoantibody Standardization Subcommittee Annual Study Group “Autoantibodies in Diagnosis and Follow up of Rheumatic Diseases”, Chicago, October 22, 2018


Establishment of the first calibrator for C1q autoantibody

Establishment of policy for interactions with industry aiming to improve Complement testing

External Quality Assessment of Diagnostic Complement

- Round 10th: October 2018 (EQA10) ➔ 154 participating labs (Australia, several in Europe, Iceland, Israel, Japan, USA, South Africa)
- Round 11th: March 2019 (EQA11) ➔ 138 participating countries (mainly Germany and Europe)
- Round 12: October 2019 (EQA12) ➔ 180 participating labs (worldwide, new countries)

Establishment of website https://www.complement.org/committee

13th Complement EQA Meeting (European Complement Congress, Madrid, 13th September, 2019)


Educational actions

• Relevance of antibody validation for flow cytometry by Tomas Kalina, Kelly Lundsten, Pablo Engel accepted for publication in Cytometry Part A

Leukocyte

QAS on going activities

- **CD Maps** ➔ analysis of the expression of CD101 to CD371

- **HLDA11 Workshop**
  - Focused on seven-span receptors and ion channels
  - Expected to generate, characterize and standardize 200 mAbs
  - Expected to characterize 30 novel CDs

- **CD66 (CEACAM) and CD300 family nomenclature** ➔ similar to the CD85 family project

- Guidelines on monoclonal antibody standardization and validation
Autoantibodies in organ-specific diseases

QAS on going activities

- Alberto Farloni resigned
- Currently looking for a new Chair for this subcommittee
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
- Shortage of international standards
- Disconnection of end-users (physicians and researchers) regarding technical nuances of immunologic tests
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