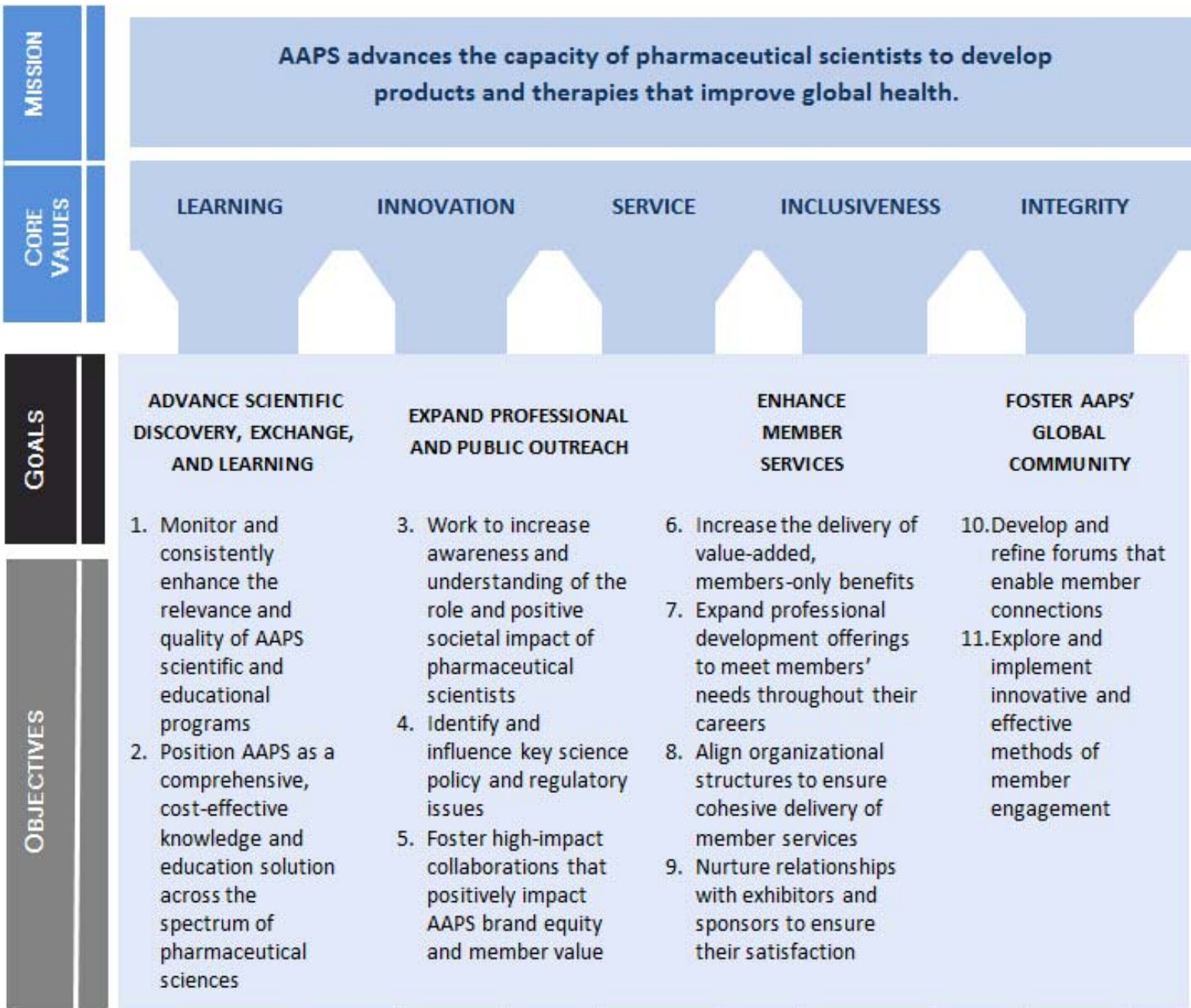


2017 LBABFG Goals

LBABFG Steering Committee

February 2017



LBABFG

Vision/Mission/Values

Vision

- LBABFG will be the premier organization worldwide for all bioanalytical scientists.

Mission

- Provide a forum to educate and promote best practices for the development, validation, and bioanalysis of macromolecules via ligand binding assays and related analytical methodologies used in the assessment of PK, immunogenicity, biomarkers and during therapeutic drug development.

Values

- *Collaboration, Communication, Inclusiveness, Innovation, Integrity, Member Focus, Member Involvement, Professional Development, Quality*

LBABFG Discussion Groups

- **Pharmacokinetic Discussion Group**
 - led by Mark Ma and Boris Gorovits

- **Immunogenicity Discussion Group**
 - led by Shalini Gupta and Yuanxin Xu

- **Biomarker Discussion Group**
 - led by Lakshmi Amaravadi and Steve Eck
 - *Flow Cytometry Sub-team (PharmaFlow)*, led by Cherie Green and Virginia Litwin
 - *Immuno-affinity LC/MS Sub-team*, led by Hendrik Neubert
 - *Immunoassay Discussion Sub-team*, led by Paul Rhyne

- **Emerging Technologies Discussion Group**
 - led by Stephanie Fraser and Fabio Garofolo

- **Regulatory Discussion Group**
 - led by Joseph Marini

- **Communications and Education**
 - led by Susan Spitz

Pharmacokinetic Discussion Group Goals

Advance Scientific Discovery Exchange and Learning

- Enhance leadership and influences in addressing issues pertaining to biotherapeutics bioanalysis supporting PK
 - **Measurement:** ADC (Antibody Drug Conjugates) Team – NBC 2017 programming accepted
- Address bioanalysis challenges for novel modalities: *therapeutic constructs with or w/o payload; mRNA and siRNA technologies; Gene editing technologies; Cell based therapies*
 - **Measurement:** Form working group to address bioanalytical issues supporting oligo nucleotides
 - **Measurement:** Wrap up discussions and plans for ≥ 1 publication summarizing outcome of team discussions
 - **Measurement:** ADC team webinars planned to promote outcome of sub-team discussions including Discovery, Pre-Clinical and Clinical support

Expand Professional and Public Outreach

- **Measurement:** Participation in at least one AAPS student outreach program
- **Measurement:** Increase number of first time volunteers and students (n>5)

Global Outreach

- Involve bioanalytical scientists from across the globe in developing programming; collaborate to develop joint programming for International Bioanalytical meetings
 - **Measurement:** ADC Team collaborating with EBF on LBABFG ADC bioanalysis Workshop
 - **Measurement:** Webinars to support year-round AAPS content and NBC
- Input on the draft ICH M10 guideline through collaboration with organizations such as BFG, PhRMA, EFPIA, GCC, and IQ Consortium

Enhance Member Services

- Develop and nurture a talent development pipeline for key leadership positions; “New faces and New ideas”

Immunogenicity Assay Discussion Group

Enhance Member Services

- Identify and ensure a smooth transition of leadership to new DG leader
 - **Measurement:** New DG leader in place in Q1 2017

Advance Scientific Discovery Exchange and Learning/Global Outreach

- Build a collaboration with TPIFG to work on:
 - Inclusion or exclusion of NAb assays in the immunogenicity testing strategy
 - Impact of newly updated FDA and EMA guidelines on testing strategy and assays
 - Importance of ADA characterization and isotyping
 - Incorporation of risk assessment in immunogenicity testing strategy
 - **Measurement:** TPIFG engaged in discussion at least 2 times in 2017
- Engage discussion group to strategize and/or partner with other DGs on:
 - Extent of assay validation for clinical studies (opportunity to partner with regulators)
 - New technologies for ADA and NAb (Emerging Technologies)
 - **Measurement:** Champions identified for each topic; feasibility assessed for potential programming topics
- Initiate discussion on ADA assay technologies for IgE measurement and for supporting Novel Modalities
 - Approaches and platforms for measurement of drug-specific IgE
 - Assays and platforms for conducting immunogenicity testing for Peptide therapeutics, anti-sense oligos, gene therapies and multi-domain therapeutics
 - **Measurement:** Topics discussed and prioritized for partnering with relevant DG or for independent effort to identify programming opportunities
- Contribute to Annual AAPS Program Content
 - **Measurement:** ...

Expand Professional and Public Outreach

- **Measurement:** Participation in at least one AAPS student outreach program
- **Measurement:** Increase number of first time volunteers and students (n>5)

Biomarker Discussion Group Goals: Immunoassay

Advance Scientific Discovery Exchange and Learning

- Maintain leadership in addressing bioanalysis issues pertaining biomarkers
 - **Measurement:** Biomarker Sample Stability paper submitted to Bioanalysis Q1-2017
 - **Measurement:** Biomarker Protein Standards sub-team White Paper to be submitted for publication early Q2-2017
 - **Measurement:** Pharma-grade Kits for Biomarkers paper is in progress, plan to complete and submit for publication in Q2-2017 (Sub-team lead- Ron Bowsher / Masood Khan)
 - **Measurement:** form at least 1 new sub team

Expand Professional and Public Outreach

- **Measurement:** Participation in at least one AAPS student outreach program (mentors, resume reviews, university visit)
- **Measurement:** Increase number of first time volunteers and students ($n \geq 2$)

Global Outreach

- Involve bioanalytical scientists from across the globe in FGs and in developing programming; collaborate to develop joint programming for International Bioanalytical meetings
- Grow LBAFG and BFG strategic collaboration

Enhance Member Services

- Develop and nurture a talent development pipeline for key leadership positions; “New faces and New ideas”

Biomarker Discussion Group Goals: Flow Cytometry

Advance Scientific Discovery Exchange and Learning

- Maintain position as the premier global group representing the use of analytic flow cytometry for drug development
 - Enhance relationships with research and clinical flow cytometry organizations, ISAC, ICCS, ICSH to ensure their activities include awareness of drug development applications
 - Strong presence at the international flow cytometry in biology research conference, CYTO 2017
 - **Measurement:** One to three /sessions focussed on current topics in drug development flow cytometry
 - **Measurement:** Publications from involvement in workshops and sessions (e.g. position/white papers)
 - Develop recommendations/position paper(s) on special topic of interest in the field
 - **Measurement:** Initiatives include Receptor Occupancy, Absolute Cell Counting, and Rare Event Analysis
 - **Measurement:** ICCS/ICSH promoted special issue of Clinical Cytometry on PNH analysis (Virginia Litwin)

Expand Professional and Public Outreach and Member Services

- Enhance learning opportunities for the field and AAPS members
 - **Measurement:** e-learning module (CYTO-U) with ISAC (Virginia Litwin and Cherie Green)
 - **Measurement:** Contributions to at least 2 AAPS Blogs
 - **Measurement:** Informal discussion meetings for topics of importance to team members (n>x)
- Support the AAPS Ambassador's Coordination Committee and University Outreach
 - **Measurement:** Participation in at least one AAPS student outreach program
 - **Measurement:** Increase number of first time volunteers and students (n>2)

Biomarker Discussion Group Goals: Immunoaffinity LC-MS/MS for Protein Biomarker Quantification

Advance Scientific Discovery Exchange and Learning

- Manuscript
 - **Measurement:** Submit for peer-review in 2Q2017
- Webinar including panel discussion, presentations from section leaders and a master slide deck that can be used for future educational purposes
 - **Measurement:** due date: 4Q2017
- Short course on IA-LC-MS/MS
 - **Measurement:** ASMS, HUPO, AAPS in late 2017/2018
 - **Measurement:** ASMS fall workshop or Sanibel or Asilomar
- Describe the 'how to'; content based on manuscript
- Support conference programming
 - **Measurement:** At least 1 original conference program for HUPO to bridge gap in relative quantification done in proteomics with expectations in bioanalytical field; plan in 2017

Expand Professional and Public Outreach

- **Measurement:** Engage scientists new to this field (LBA, SM LCMS and proteomics; n≥5)
- **Measurement:** Plan for a Webinar in 2018 and produce draft slides- by Q4-2017

Emerging Technology Discussion Group Goals

Advance Scientific Discovery Exchange and Learning

- Real-time Measurement Team
 - **Measurement:** Identify and review at least 1 new technology that impacts real-time measurement
 - **Measurement:** Submit at least 1 programming proposal for 2018 AM360

- Emerging Technologies Software Validation Team
 - **Measurement:** Developed new approach for system analysis; publication summarizing team's successful interactions with Singlex on platform validation in progress

- Assay Multiplexing and Throughput Team
 - **Measurement:** Identify at least 2 technologies with impact on multiplexing, automation and/or high throughput; publish manuscript in 2017
 - **Measurement:** Deep dive publication on Simoa technology in collaboration with Sensitivity team
 - **Measurement:** Submit at least 1 programming proposal for 2018 AM360

- Assay Sensitivity Team
 - **Measurement:** Survey of biotech and biopharma about unmet needs for sensitive assay technologies
 - **Measurement:** New applications for evaluation and draft a manuscript
 - **Measurement:** Contribute to deep dive Simoa evaluations and publication of results

- Assay Interference Team
 - Focus on Hybrid LBA/LCMS to minimize assay interferences; Emerging approaches on PK, Biomarkers and ADA Assay
 - **Measurement:** Draft manuscript
 - **Measurement:** Submit at least 1 programming proposal for 2018 AM360

Emerging Technology Discussion Group Goals cont.

Expand Professional and Public Outreach

- **Measurement:** Participation in at least one AAPS student outreach program (mentors, resume reviews, university visit)
- **Measurement:** Increase number of first time volunteers and students (n≥4)

Global Outreach

- Involve bioanalytical scientists from across the globe in FGs and in developing programming; collaborate to develop joint programming for International Bioanalytical meetings
- Participate in LBAFG and BFG strategic collaboration

Enhance Member Services

- Develop and nurture a talent development pipeline for key leadership positions; “New faces and New ideas”

Communications and Education

Expand Professional and Public Outreach

- Participation in the AAPS student outreach program
 - **Measurement:** visit at least 8 universities that were not visited in 2016
 - **Measurement:** every LBABFG Steering Committee member will commit
- Increase number of first time volunteers and students in every primary discussion group
 - **Measurement:** Engage with the LBABFG student rep for each quarterly newsletter
 - **Measurement:** Reaching out to first time volunteers (n>4) for contributions to the newsletter
 - **Measurement:** Create a year-round 'volunteer interest and assignment' process for first time volunteers and students

Enhance Member Services

- Increase presence on social media
 - **Measurement:** generate at least 2 AAPS Blogs
 - **Measurement:** launch Facebook, and Twitter LBABFG sites; promote use
 - **Measurement:** Drive the "Ask our Members" and "Ask our Experts" outreach in each e-blast and newsletter and on social media sites
- Produce 4 high quality LBABFG newsletters and monthly e-blasts
 - **Measurement:** Confirm click rate; post through LinkedIn

European Representative Goals

- Serve as an international liaison to the EU bioanalytical community and provide LBABFG updates on the activities/meetings of European scientific organizations in the field of bioanalysis