2010-2012 Strategic Plan

Clinical Pharmacology and Translational Research Section
American Association of Pharmaceutical Scientists (AAPS)

PREAMBLE

This 2009-10 update of the 2006 Strategic Plan for the Clinical Pharmacology and Translational Research (CPTR) Section of the American Association of Pharmaceutical Scientists (AAPS) establishes a course of direction for the Section in all of its activities during the 1-3 year horizon (2010 – 2012). It is consistent with the vision and goals of the current AAPS Strategic Plan and builds upon the previous accomplishments of its members. The plan serves the needs of the members of AAPS and CPTR Section and will possibly influence some public health regulatory policies.

The Strategic Plan is a living document to which modification should be made at least once every year to assure that it remains current and relevant. The plan is flexible enough to enable the Executive Committee of the Section to respond to emerging changes in the clinical and translational research and development environment. (2010 Goal: The CPTR EC will update the CPTR Strategic Plan to guide the activities of the Section for the 1-3 year horizon)

Based upon the Strategic Plan, the CPTR Section Executive Committee will develop specific objectives and actions steps each year. Identification, timing, prioritization, and implementation of the action steps are the responsibilities of the CPTR Section Executive Committee.

The CPTR Section Executive Committee consists of the following in 2010:
  Chair: Rajesh Krishna
  Chair Elect: Dale Yu
  Vice-Chair: Donald Mager
  Past-Chair: Peter Bonate
  Secretary: Stacey Tannenbaum
  EC Liaison: Peter Crooks
  Student rep: Pavan Kumar Vaddady

Vision

The Clinical Pharmacology and Translational Research Section will be the premier section of AAPS dedicated to public health and clinical discovery, safety, efficacy, and translational research and development of human pharmaceutical products. Specifically, the charter of CPTR includes issues central to clinical pharmacology and applied pharmacotherapy. These include, and not limited to, clinical safety, adverse drug reactions, special populations, clinical pharmacokinetics and pharmacodynamics,
translational biomarkers, computational and systems biology, clinical trial design and simulation, and pharmacogenomics. The scope of the CPTR section will extend beyond the development of human pharmaceuticals into the post-marketing phase including post-marketing surveillance, health economics, and epidemiology, as well as aspects related to drug utilization, public health and patient care.

**Mission Statement**

The Clinical Pharmacology and Translational Research Section of AAPS provides a dynamic forum for the exchange of knowledge among scientists engaged in clinical research to enhance their contributions to innovative, science-based solutions for development and safe use of human pharmaceuticals.

**Values**

1. **Clinical and translational research framework:** The CPTR Section is committed to enhancing public health by fostering the translational and clinical development and rational use of human pharmaceutical products.
2. **Member recruitment and advancement:** The CPTR Section is committed to expanding membership and extending interactions with all relevant healthcare professionals, including clinical, academic and physician scientists, practitioners, drug developers and regulators engaged in the science of translational and clinical pharmacology. The Section is particularly committed to extending interactions and joint programming with physicians and public health professionals, as part of its ongoing mission.
3. **Education:** The CPTR Section is committed to offering quality programming, and relevant scientific publications and communications to its members. Similarly, the CPTR section embraces the role of educating the next generation of healthcare scientists which will support the various aspects of drug development, regulation, and patient care.
4. **Policy:** The CPTR section is committed to advancing policy and outreach in the scientific community in core areas of expertise within the Section, such as developing white/position papers.

**Critical Success Factors & Goals**

1. **Clinical and translational research framework:** An objective of AAPS is to be the primary advocate for the pharmaceutical sciences in influencing and developing public policy. The CPTR Section is the clinical voice of AAPS. The section is the forum for networking for various clinical disciplines, including: clinical pharmacology, clinical research and development in many therapeutic areas, translational research, applied pharmacotherapy and clinical pharmacokinetics and pharmacodynamics. One of the strengths of the CPTR Section is the diverse experience and expertise of its members.
a. Participate in AAPS Jamborees for the NBC and Annual meetings to enhance interaction and collaborative program with other Sections and Focus Groups

b. Support of the AAPS QMBDD Initiative
   - Develop programming to advance QMBDD initiative.
   - Support the AAPS QMBDD Task Force.

c. Science based initiatives to influence public and regulatory policies
   - Provide a forum to discuss the emerging scientific developments in the clinical arena.
   - Identify and develop programs to advance clinical and translational sciences.
     - Develop disease area “Theme Stream” by picking at least one disease area based programming every year. 2010 focus is on global health (e.g., neglected diseases) as per AAPS 2010 presidential goal.
   - Identify and develop programs in the emerging areas of regulatory interest (Eg: Critical Path Initiative, NIH Roadmap, Drug/Disease modeling, Imaging, QT analysis)
     - 2010 Goals:
       1. Focus on chronic diseases, especially orphan and neglected diseases and alignment with global public health initiatives. Encourage the broader use of public health issues and risk/benefit in CPTR programming, both alone and in collaboration with other clinical societies (ASCPT, ACCP, etc)
       2. Focus on public-private partnerships and negotiations in the pre-competitive space. 2010 open forum will likely focus on pre-competitive knowledge sharing
   - CPTR will encourage debate on topics related to clinical and translational research, e.g. to FDA initiatives and guidance documents, NIH initiatives etc. This will be accomplished by organizing Workshops, Hot Topics and Open forums on these emerging topics.

2. Member recruitment and advancement: The CPTR Section is one of the smaller scientific sections of AAPS, but one of the sections with the largest growth potential. A strategy is needed to better define the diverse nature and expertise of the section and to enhance the growth of the section by attracting new members into the organization. It is highly desirable to involve more members in Section activities, and all members should be encouraged to participate in some capacity. The formation of related focus groups needs to be nurtured and their growth should be supported to meet the scientific needs of the membership. Student membership and participation should also be encouraged to ensure the future growth and vitality of the CPTR Section. The CPTR section also needs to reach out to other CPTR area societies for more collaborative programming.
Section name change from Clinical Sciences to Clinical Pharmacology and translational Research was approved by the AAPS EC in fall 2006 and has helped us to better define membership of the CPTR Section.

a. Member recruitment
   o Increase number of focus groups with primary affiliation with CPTR Section. CPTR’s current primary FG affiliations are
     o Modeling and Simulation
     o Pharmacogenomics (PGx)
     o Translational Biomarkers
     o Pharmacoimaging
     o Protein aggregation and biological consequences
     o Support 2010 charter of systems biology focus group
     o Dermatopharmaceutics
     o Drug transport
     o Microdialysis
     o Pharmaceuticals in global health
     o Consider joint focus groups with other clinical societies (ASCPT)
     o Outreach to prospective AAPS members, specifically clinically trained clinical pharmacologists (e.g., Pharm.D.s, MDs, PhD clinicians).
       o 2010 Goal: Assess opportunities for outreach via programming topics of interest to other organizations 2010 suggestions includes the topic of “Translational Biomarkers” and the following venues
         1. Joint programming of Workshop with ACCP/ASCPT (eg Diagnostics workshop)
         2. Joint ACCP/AAPS symposia slot at AAPS Annual meeting. 2010 symposium "Genomics issues and solutions in oncology drug discovery and development"
     o Enhance the membership base of the section by attracting new members working in the emerging area of clinical development of biotherapeutics.

b. Member advancement
   o Engage members in various guidance committees: One of the key strengths of the CPTR Section is the diverse experience and expertise of its members and their willingness to get involved in leading Section activities. A strategy is needed to involve more members in Section activities. The section should offer leadership opportunities to members via Section and Focus Group activities.
     o Create think-tanks or expert opinion working groups within CPTR as a means to advance section outreach and member
engagement objectives. 2010 focus on 3 theme streams, namely pediatrics, pharmacometric model validation, and PGx.

- **2010 Goal:** In 2010, the section leadership will focus on creating/sustaining various committees that will guide and advice the CPTR Executive Committee on various aspects. For Example,
  1. Nominations committee for fellows
  2. Awards Committee
  3. Open Forum Committee
  4. Meritorious manuscript committee for 1) public health, and 2) Modeling and Simulation

**c. Member recognition**

- Awards are an important part of any professional organization to recognize the outstanding achievement of its members. Continue to nominate members for Fellow status in AAPS.
- Maintain CPTR Research Achievement Award as one of the most prestigious AAPS awards to enhance the credibility and visibility of the CPTR section.
  - 2009 recipient: Marc Ratain, MD
- Maintain active involvement in the PPDM/CPTR Graduate Award Symposium to recognize outstanding achievement of graduate students.

**d. Member involvement**

- Encourage member involvement by sending out listserv mailings on topics of interest to the members.
- Encourage communication within focus groups, for example, via newsletters (PGx focus group).
- Send entire membership an annual update on Section goals via email/newsletter or video (2010 Goal: do this by 1Q10) and a membership meeting annually (Annual Goal: Membership meeting at the AAPS Annual Meeting)
- Keep abreast of member interests and current issues in various therapeutic areas

3. **Education:** Personal and professional development are of paramount importance to growing and maintaining the Section membership. Development includes: learning new skills, filling gaps in formal educational training and updating existing skills. For pharmaceutical professionals, continuing education is mandatory for demonstration of continuing competency, and in other cases continuing education certification is mandatory to maintain professional licensure. CPTR section members come from a
broad range of educational backgrounds, but share many common interests in clinical and translational research. Thus, the CPTR Section should optimize AAPS and Section resources to facilitate the educational needs of its membership. Likewise, the section should actively promote student participation with tangible evidence including student-initiated programming and involvement in section activities.

a. Education of members and scientific community
   o A major revision of CPTR Web site will be undertaken in 2010 to reach a broad cross-section of Section and AAPS members, and potential new members. The website plans will mirror AAPS' objectives and will be regularly updated in order to meet the section’s needs.

b. Offer high quality programming at the AAPS National Meetings.
   o Develop programming ideas for submission to Annual meeting. The Section should identify a mechanism to develop programming of broad interest. In addition, the Section should work to develop a method incorporate continuity of programming ideas.
   o Develop programming ideas for submission to NBC meeting. The Section should reach out to members in the Biotechnology sector to develop ideas and topics for the NBC meeting.

c. Offer high quality Short Courses and Workshops.
   o 2010 Goals: Develop one or more ideas for Short Course or Workshop

d. Organize programming events in collaboration with other sections and organizations (This overlaps with Member Recruitment, Outreach)
   o Because of the multidisciplinary nature of pharmaceutical research and development, the CPTR Section should develop programming in cooperation with other AAPS Sections or scientific organizations. Activity participation in the annual meeting and NBC jamborees is an important venue for interaction with other sections. Opportunities to sponsor or cosponsor national or international symposia, workshops and short courses should be explored to attract new members and enhance the Section’s visibility.
     o Foster collaboration with American College of Clinical Pharmacology (ACCP): Joint Symposium at AAPS Annual meeting & participation in ACCP programming events
     o Foster collaboration with American Society for Clinical Pharmacology and Therapeutics (ASCPT). Consider for 2010, a joint workshop with ASCPT (e.g., diagnostics)

4. Policy: CPTR membership is multi-disciplinary and comprises a diverse pool of scientists in academia, industry, and regulatory institutions with a common goal, to advance the field of clinical pharmacology and translational research. Each year, CPTR contributes quality programming in areas of strategic importance to the community, and
in particular to clinical drug discovery, development, and use. The collective information gained from programming (sunrise, short course, symposia, open forum, and roundtables), while substantial, timely, and state of the art, is often not effectively harnessed. Key opportunity exists to effectively leverage information gained from programming activities and develop thoughtful contributions that will increase the reach and standing of the Section to the scientific community. The vision of the policy initiative is to enhance CPTR visibility and influence in the clinical pharmacology and translational research community by developing expert opinion contributions in key functional area strategic areas. By chartering expert opinion think-tanks (or small working groups) on strategic theme-streams, the goal is to develop a position/white paper as a CPTR sponsored initiative after thoughtful debate on specific aspects within a specific theme stream that are most relevant to CPTR objectives. Such an initiative is conducive to leveraging learnings from a previously conducted programming event and might include, as suggestions, aspects like risk/benefit, dose selection strategies, translational paradigms, etc within those theme streams. The position/white paper will be showcased at the CPTR website and will be submitted as a peer-reviewed contribution to an AAPS journal (standard peer-review principles apply) or the AAPS Newsmagazine. As part of CPTR focus for 2010, the goal is to charter a think tank of experts within 3 potential theme streams, with the aim to initiate one. The chair of the think tank will be nominated by the CPTR EC and the chair will solicit membership from the CPTR community and the appropriate aligned focus group.

2010-2012 theme streams could include:

- Pediatrics (pediatric drug development, PIPs, etc).
- Pharmacometric method validation
- QTc
- PGx (translational/personalized medicine)