Standard of Care Working Group

Update

Co-Chairs: Manal F. Abdelmalek, MD, MPH (Duke University)
Sven Francque, MD, PhD (Antwerp University Hospital)

Lead Group: Oliver Glass, PhD (Duke University)

First Organizational Meeting
September 11, 2017

Working Group Members

- Manal Abdelmalek, Duke University
- Anuli Anyanwu-Ofili, Janssen
- William Baldyga, University of Illinois at Chicago
- Jean Chan, Conatus Pharmaceuticals
- Edgar Charles, Bristol-Myers Squibb
- Lara Dimick-Santos, U.S. FDA
- Claudia Filozof, Covance
- Sven Francque, Antwerp University Hospital
- Michael Fuchs, McGuire VA Medical Center
- Oliver Glass, Duke University
- Katherine Greene, Forum for Collaborative Research
- Morten Hansen, Novo Nordisk A/S Denmark
- Stuart Kendrick, GlaxoSmithKline, Inc.
- Gadi Lalazar, The Rockefeller University
- Alex Lugovskoy, Morphic Therapeutic
- Veronica Miller, Forum for Collaborative Research
- Philip Newsome, University of Birmingham
- Mazen Noureddin, Cedars Sinai Medical Center
- Eric Olson, GlaxoSmithKline, Inc.
- Stephanie Omokaro, U.S. FDA
- Melissa Palmer, Shire Pharmaceuticals
- Rajnish Saini, GlaxoSmithKline, Inc.
- Jörn Schattenberg, University Medical Center Mainz
- Reshma Shringarpure, Intercept Pharmaceuticals
- Richard Torstenson, Novo Nordisk A/S Denmark
- Vincent Wong, The Chinese University of Hong Kong

Mission

Create a framework and open dialog between all stakeholders on how to “standardize” the standard of care for NASH in the context of clinical studies

Goals of Working Group

- Review current SOC
- Establish *recommendations* (not guidelines) for standard approaches to NASH for clinical trials:
  - Physical activity
  - Diet
  - Validated approaches to capture such data for trials
  - Consideration on clinical study designs to account for different standards (diet/ activity) globally

Goals of Working Group

- Propose standard which manages co-morbidities (lipids, glycemic control etc.) within scope of existing practice guidelines
- Implementation of such standards in clinical trials
  - Feasible,
  - Cost effective
  - Easy to implement
  - Sustainable over the duration of trials (2-5+ years)

Scope of Working Group

- Focus on NAFLD / NASH (F0-F3) only
  - Exclude cirrhosis / decompensated cirrhosis
- Adults and pediatrics
- Recommendations for standard approaches to management of lifestyle and metabolic factors that contribute to disease activity will be discussed in one manuscript.

Proposed Outline

- Background
  - Importance of lifestyle in relation to NAFLD
  - Lack of standardization of lifestyle modification
  - Lack of standardization in capturing lifestyle data for clinical studies
- Introduction
  - Importance of standardization
    - Interpretation of results and efficacy data and associated confounders
    - Capture the impact of being in a study on behavior modifications over time
    - Standardize patients to be enrolled “metabolically stable vs metabolically optimized”
- Literature Review
  - Review current practice
  - Review current measure / monitoring tools

Proposed Outline

- Recommendations
  - Diet/ exercise
    - What is provided
    - Who is providing
    - How it is captured
  - Treatment of comorbidities
    - Standardizing approaches
  - Consideration of “lead-ins” to ensure stability
- Limitations of a proposed standard
  - Differences in guidelines
  - Differences in regional practices
  - Differences in reimbursements
  - The more “standardized” the SOC, the less generalizable study results become as study cohort will not be representative of “real-world”.

Next Steps

- Review how to capture data
- Review current validated tools in
  - Obesity studies
  - Diabetes studies
- Develop a draft manuscript by January 2018.
- Final Manuscript Feb/March 2018