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AAPS Connection

American Association of Pharmaceutical Scientists September 2015

AAPS Workshop on Nanotechnology in Personalized Medicine

October 25, 2015
Orange County Convention Center, Orlando, Fla.

The workshop on Nanotechnology in Personalized Medicine in 2015 assembles the leading experts to address the latest advances in nanotechnology for personalized medicine application. Nanoparticles in varied chemistry and architecture such as nano-ceramic composite, carbon nanotubes, nanofibers, micropatterned nanosheets, nanogels, degradable dendrimer, and micelles will be discussed for their applications in bone regeneration, lung repair, gene therapy, stem cell tissue engineering, brain and eye disease treatments, cancer therapy, biosensing, and bioimaging.

In addition, this workshop also addresses scientific, technical and funding opportunities and challenges in applying nanotechnology to personalized medicine.

Goals and Objectives

Nanotechnology and personalized medicine are two of the most rapidly emerging areas that can potentially lead to revolutionary industrial changes for improving health care and health outcomes. Nanotechnology provides the opportunity for using nanoparticles to deliver drugs to the targeted sites to treat diseases with reduced toxicity or side effects and improved drug bioavailability (nanotherapeutics); sensor specific molecules and visualize cell trafficking and gene expression in vivo for diagnosing diseases (nanosensoring and nanodiagnostics); improve DNA sequencing and SNP analysis (nanosensoring and nanodiagnostics); build scaffolds to grow cells to help reproduce or repair damaged tissues (nanotissue engineering); fabricate 3-D nanostructured electrodes self-powered by biofuel cells for neuroelectronic interfacing (nanomedical devices); and build future nanorobots by means of mechanosynthesis guided by molecular machine systems (molecular nanotechnology).

Personalized medicine provides for customized healthcare tailored on an individual basis to the uniqueness of the patient's own genetic information. Application of nanotechnology in personalized medicine identifies the overlapping interests of these two main areas with the potential to usher in a new era of treating and diagnosing diseases in multi-modality fashion at the nano scale while tailored to the individual characteristics of each patient.

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For more information, please visit www.aaps.org/MPN/

AAPS Workshop on Specific Population Drug Dosing Recommendations: Shifting from Clinical Studies to Predict and Confirm

October 24–25, 2015
Orange County Convention Center, Orlando, Fla.

Patients in some 'specific populations' may have altered pharmacokinetics to an extent that their posology should be

altered. Thus, current standards are to perform 'specific population' studies before approval, if these patients will likely need the drug. However, for certain subpopulations (e.g., burn patients), it may be years before dosing information is available.

It is becoming clear that for some subpopulations, examination of existing data will lead to models that predict PK well enough to allow new development and regulatory paradigms. One possible scenario would be to have prediction based labeling recommendations (i.e., without performing human trials) with post marketing confirmation. Such paradigms would eliminate the need to perform unnecessary human trials, including those where the participants receive no medical benefit, and could allow resource redirection towards specific populations that are less well studied.

This workshop is the first step toward creating a self-sustaining learning process that will allow continuous improvement in dosing predictions in specific populations. The workshop will examine the challenges in developing these models and generate ideas for creating research and regulatory paradigms that allow this more efficient use of information, resources and patients.

The objectives of this workshop are:

- Illustrate the problems with the current paradigm and define the benefits and risks of this prediction-based approach.
- Describe the current state of the art for models describing sub-populations and how well these models predict.
- Consider what evidence is needed to decide a model adequately predicts a subpopulation in order to provide dosing recommendations and how to decide what is needed in particular instances, e.g., decision tree.
- Consider possible ways for collaboration (including funding), on the establishment of databases and data sharing in order to efficiently develop and later improve models.
- Consider the process for implementing change in the drug development and regulatory paradigms supporting this change when warranted, including ways to achieve global harmonization.

For more information, please visit
www.aaps.org/Subpopulations

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Orange County Convention Center, Orlando, Fla.

October 24–25, 2015
AAPS Workshop on Specific Population Drug Dosing Recommentations: Shifting from Clinical Studies to Predict and Confirm
Orange County Convention Center, Orlando, Fla.
www.aaps.org/Subpopulations

October 25, 2015
AAPS Workshop on Nanotechnology in Personalized Medicine
Orange County Convention Center, Orlando, Fla.
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October 25–29, 2015
2015 AAPS Annual Meeting and Exposition
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