Cancer has been one of the most important and challenging disease in medicine. Although a significant progress has been made in the genomics and molecular biology of cancer in last fifty years patients still die of their disease. Therapeutic use of tumor antigen specific monoclonal antibodies, tyrosine kinase inhibitors, adoptive immunotherapy with LAK /TIL cells, cellular immunotherapies and recently discovered checkpoint inhibitors and CAR-T Cells can be listed as successful list of anti-cancer treatments. As we realize, the limitations of our approaches to cure cancer have been hampered due to vast array of molecular defects that define various cancers and subtypes. Since 2012, NCI and NIH have been discovering unique therapies that can treat an individual’s cancer based on specific genetic abnormalities of that person’s tumor type. This is a new era of oncology practice where completely mapped genetic and molecular profile about a patient’s cancer can be routinely employed for his/her therapy. Precision Medicine is defined as “Translation of basic science to routine testing, screening, diagnosis and therapy in cancer”. Precision medicine uses massive data (Big Data) network that aggregates and analyzes information from large patient cohorts, healthy populations, experimental organisms and reaches toward disease mechanisms and precision diagnosis and therapy for each individual. In precision medicine, sequencing cancer genomes is only the first step in understanding the disease. Then, we have to find out which genetic changes / mutations are playing a role as “drivers” in the development of cancer. Transcription Factors (TFs) serve as “master regulators” control most of the genes in the gene signatures of cancers. If one wants to put all the data/big data in perspective system biology, experimental biologist, molecular biologist, expert in bioinformatics and clinical researcher must be employed in the team to translate cancer genome findings (bench) to the patient care (bed-side). President Obama has expressed quite a strong conviction that science offers great potential for improving health and announced the Precision Medicine Initiative on January 15th, 2015 (www.whitehouse.gov/precisionmedicine). This important initiative has two components, namely “a near-term focus on cancers” and as a second aim to “generate knowledge applicable to the whole array of health and disease”. There will be many steps ahead to have a success in speeded the application process and regulatory affairs of this novel therapeutic challenge in cancer medicine for 21st century.

**D-02 QUALITY ASSURANCE IN ENDOCRINE LABORATORIES**

Diler Aslan
Pamukkale University, Faculty of Medicine, Department of Medical Biochemistry, Denizli

Small changes in the levels of hormones and related biomarkers are invaluable as specific and earlier indicators of endocrine disorders and diseases than appearance of physical symptoms. Clinical practice guidelines recommend heavily the early laboratory testing. Accurate and reproducible measurement is challenging because of some characteristics of these molecules such as their chemical natures, existence in too small amounts, diurnal variations and free forms as well as bound forms in the circulation, and too short half-lives. Therefore, analytical techniques have been evolving continuously in order to produce more reliable and accurate measurement procedures for high quality outcomes. The measurement procedure characteristics and the measurand nature should be known well. Endocrine tests are also influenced heavily by variations in the total testing process. In this context, quality management system which is composed of quality assurance and quality control processes should be established throughout the healthcare institution. Laboratory can be structured according to the ISO 15189:2012, the medical laboratory accreditation standard. National standardization programs are organized for harmonization of hormone measurements. Performance of hormone and related molecules measurements is under responsibilities of the manufacturers/vendors of measurement systems, laboratories, clinicians, and the regulatory authorities. In this context, the following topics are considered in this talk:

- Laboratory quality assurance process and quality control processes, and differences
- Responsibility areas of manufactures, laboratory and regulatory authority in the context of the IV license cycle
- Characteristics of hormone measurement procedures
- Harmonization and standardization of hormone assays
- Quality assurance of endocrine laboratories according to the accreditation standard (ISO 15189:2012)
- The status in Turkey versus in the world.

In summary, quality assurance in the endocrine laboratories is explained according to the related steps of the IV license medical device life cycle (from production to the last users) with the organizational, national and global point of view by focusing on patient safety and healthcare expenditures.