Analytical and Clinical Validation of Automated Bone Scan Index (BSI) as a Biomarker Indicative of Treatment Efficacy

Aseem Anand, CCRP
PhD Candidate
The issue – Qualitative and Subjective interpretation

Case

*metastatic prostate cancer Patient, who received Abiraterone.*

Impression
A Improvement
B Stable disease
C Progression

ANT

POST

17%
22%
61%

regression stable progression

N=58
Clinical Trial Recommendations:

- **PCWG2**
  - Does not measure response only confirms progression
  - Sclerotic diffused disease
  - Complete manual labor intensive

- **FDA – Central Reads**
  - Local sites know the patient better
  - Complete Manual Process
Automated BSI Combines the recommendation of FDA and PCWG2 - Lesion Classification and Lesion Count

Segmentation of Skeleton → Normalization → Hotspot Detection → Hotspot Classification → Bone Scan Index (BSI)

**Segmentation of Skeleton** is based on 2D image registration of an Atlas over the patient’s Bone Scan.

**Artificial Neural Network (ANN)**

**Hotspot classification** is based on Artificial Neural Network (ANN) which is a complex computer algorithm making non-linear decisions based on given data parameters.

Video 1

Video 2
Automated BSI a quantitative biomarker

- Automatic lesion detection and classification
- Automatic tracking of old and new lesion and its location
- Automatic calculation of BSI
- Electronic Reports
1. Analytically validation

- Reproducibility
- Accuracy
- Linearity
- Specificity
- Sensitivity

Biomarker Qualification

Clinical Validation (Context of Use)

Analytical Validation (Performance Characteristics)
1. Clinical Validation

Automated BSI as an analytically validated AND quantitative CLINICAL TOOL
Swedish Metastatic Prostate Cancer Consortium (M1-PCC)

Dr. Anders Bjartell
Dr. Lars Edenbrandt

Dr. Michael Morris

Dr. Lawrence Schwartz