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

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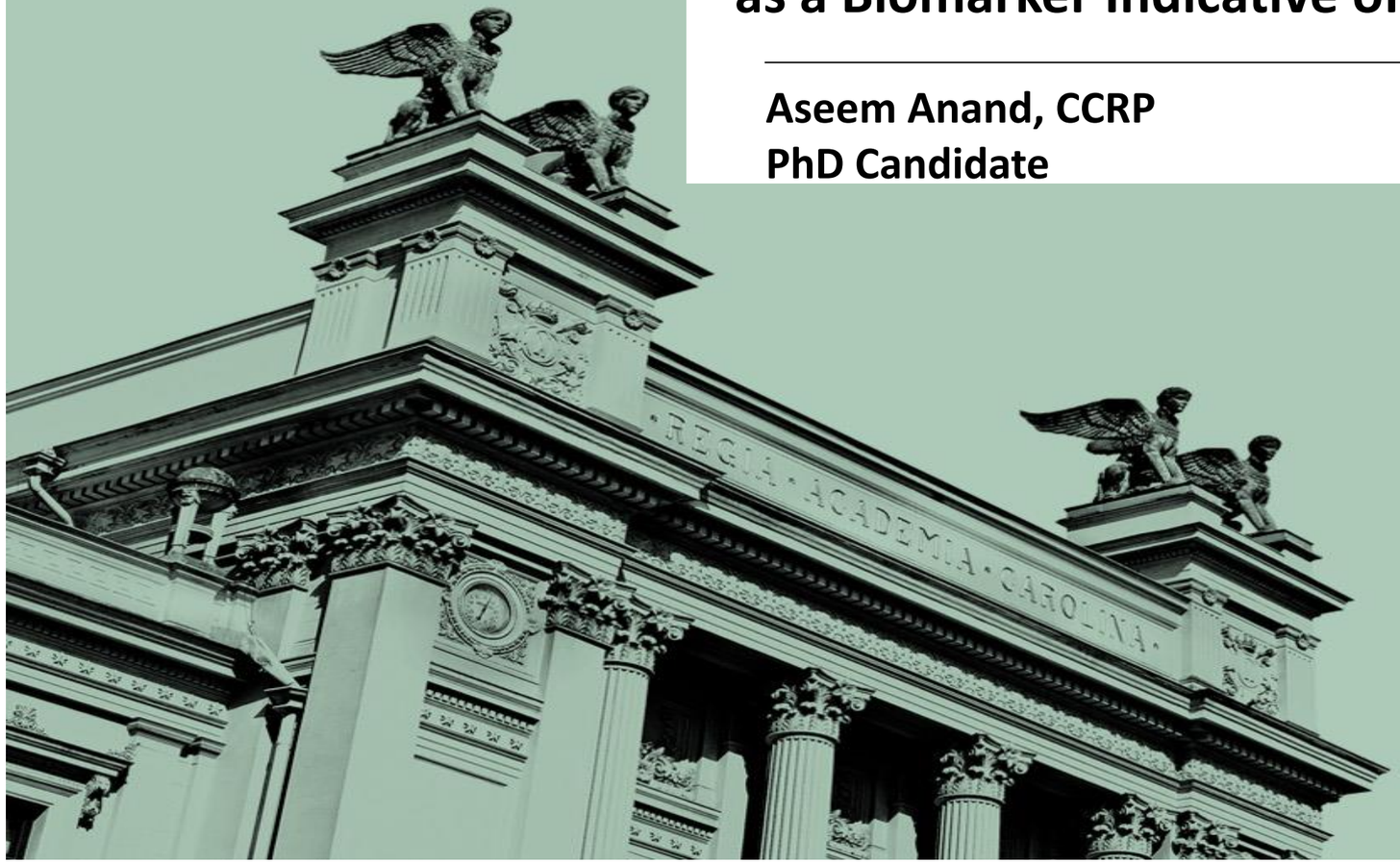
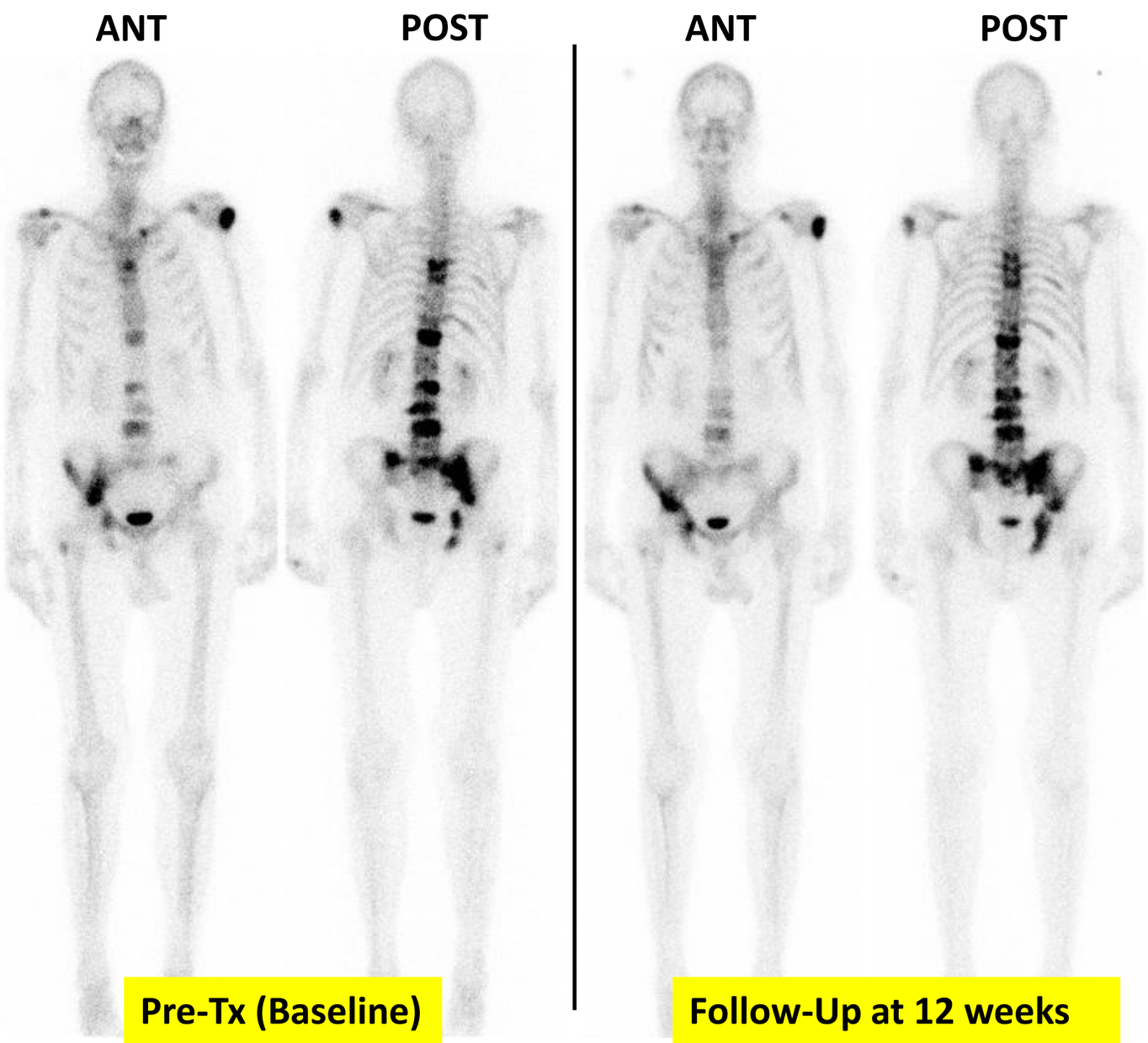


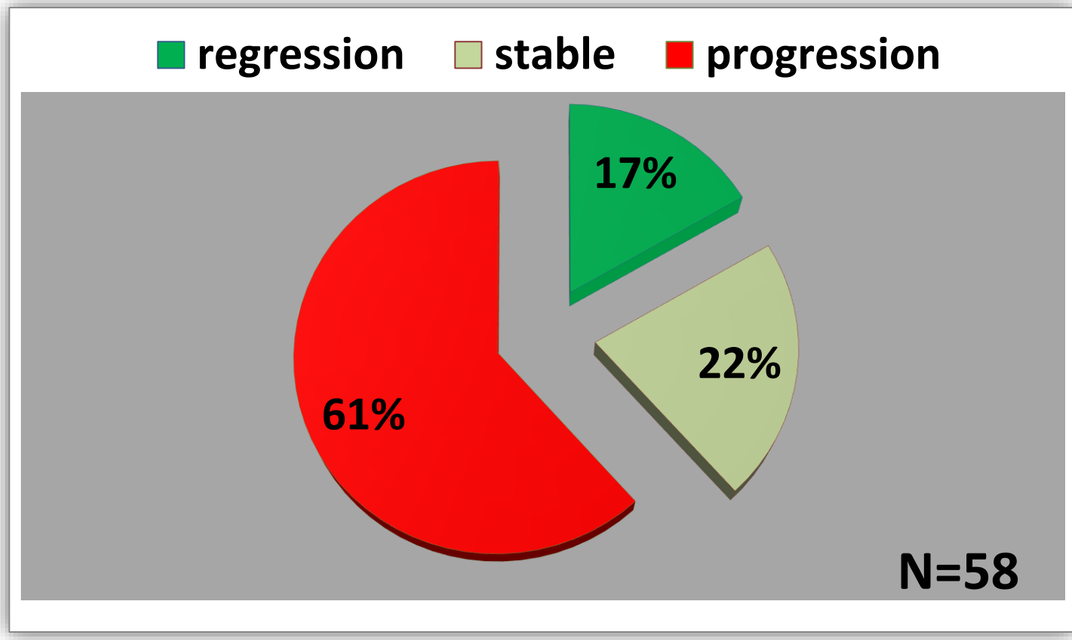
The issue – Qualitative and Subjective interpretation

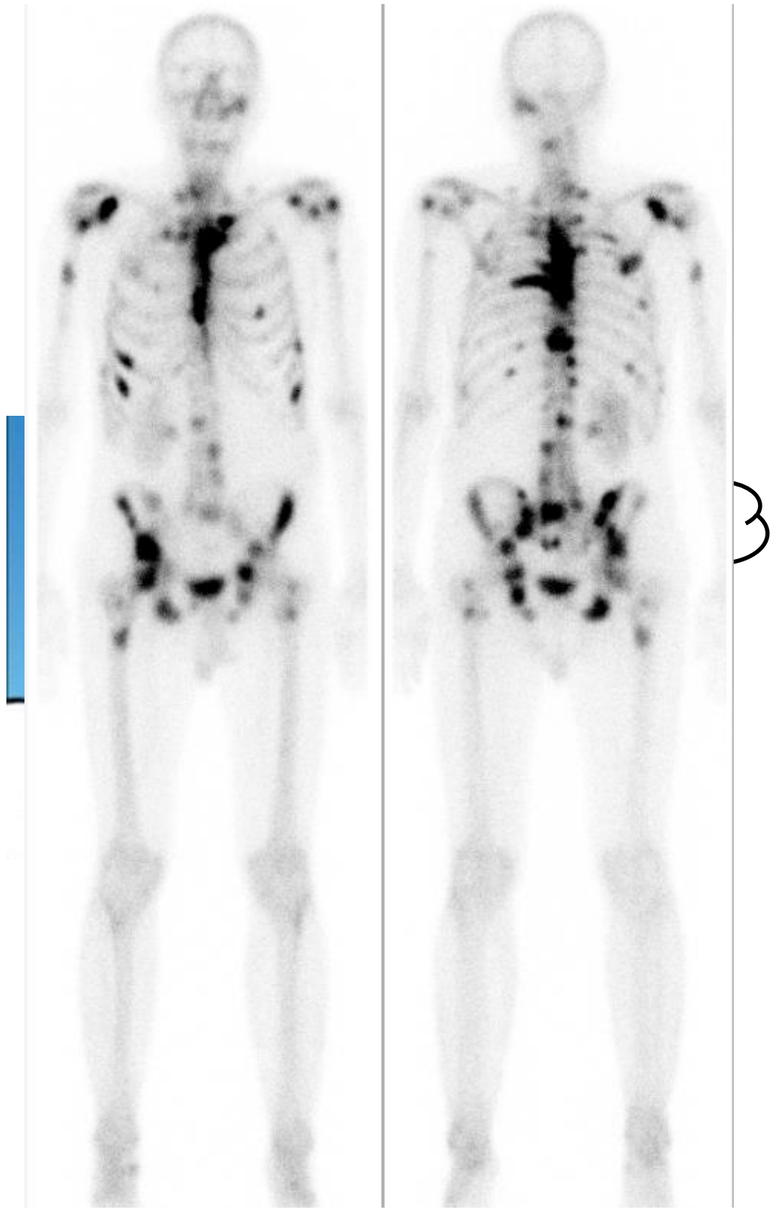


Case

metastatic prostate cancer Patient, who received Abiraterone.

Impression
A Improvement
B Stable disease
C Progression



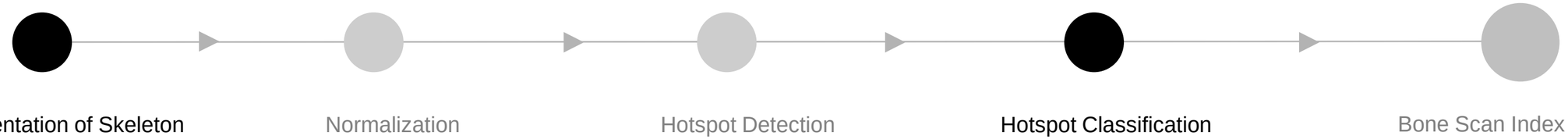


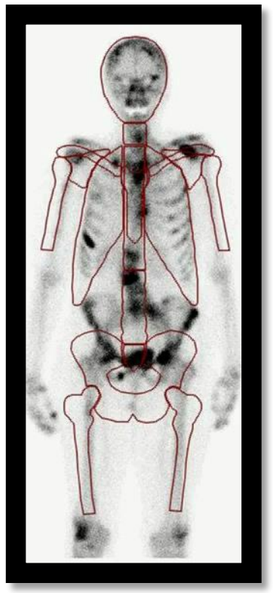
Clinical Trial Recommendations:

- **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

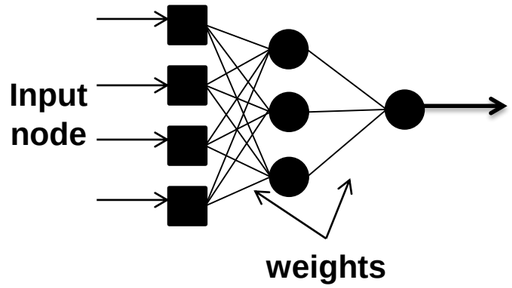


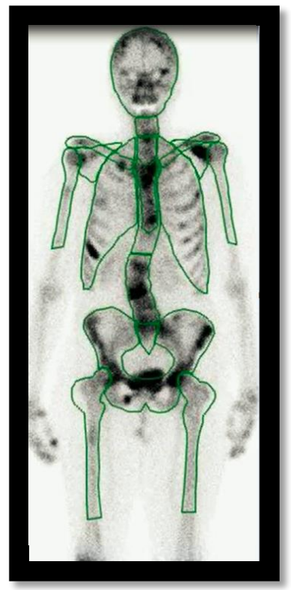


Video 1

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

Artificial Neural Network (ANN)

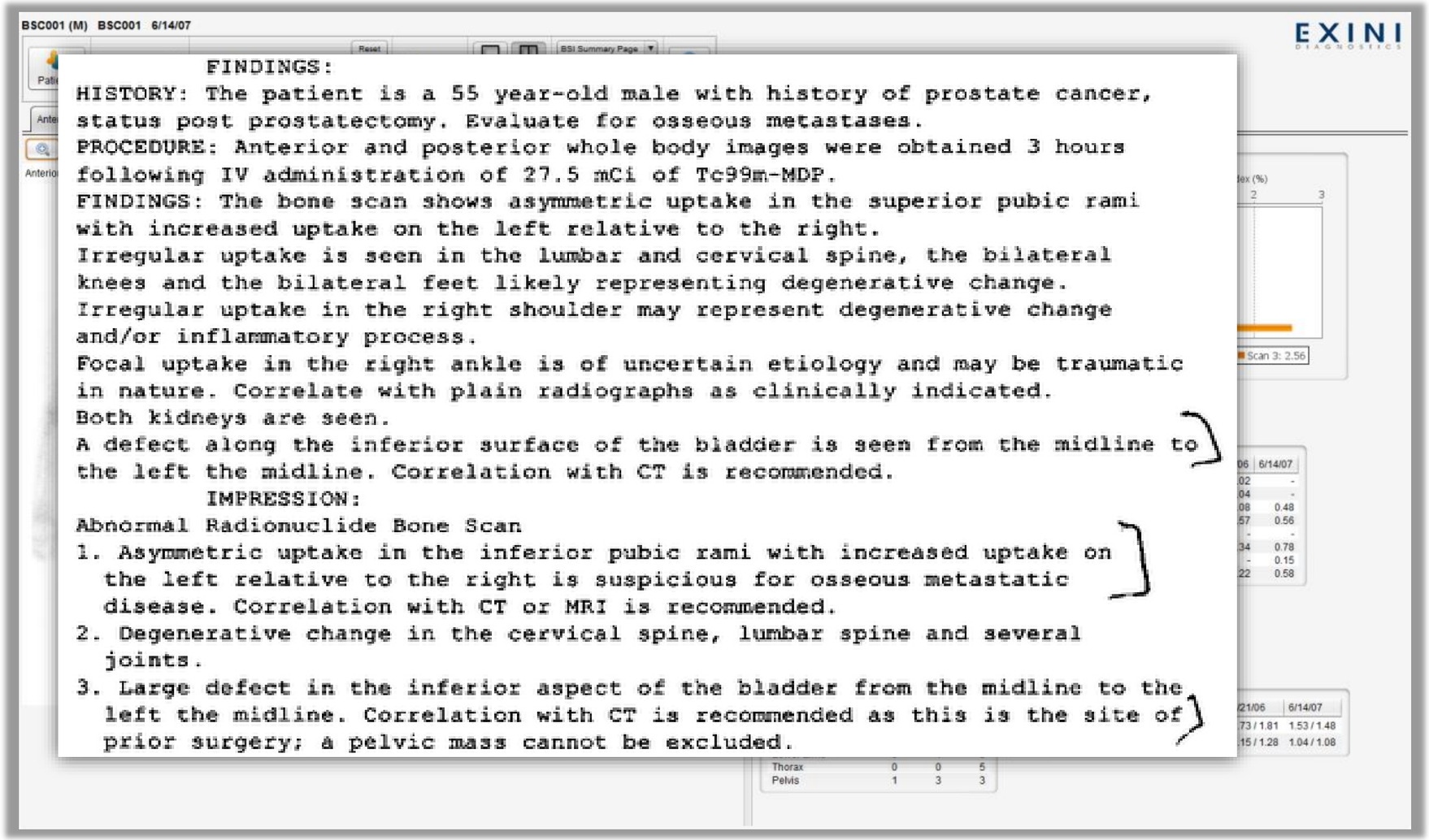




Video 2

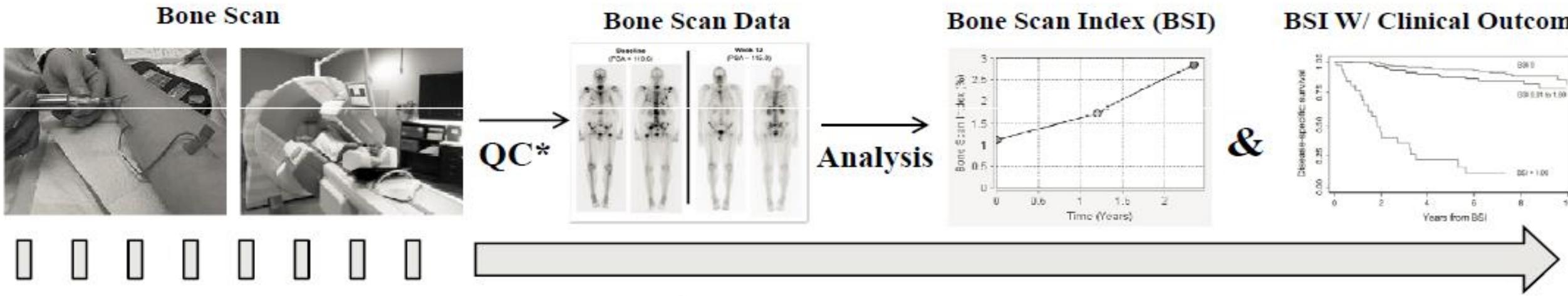
Hotspot classification is based on Artificial Neural Network (ANN) which is a complex computer algorithm making non-linear decisions based on given data parameters.

Automated BSI a quantitative biomarker

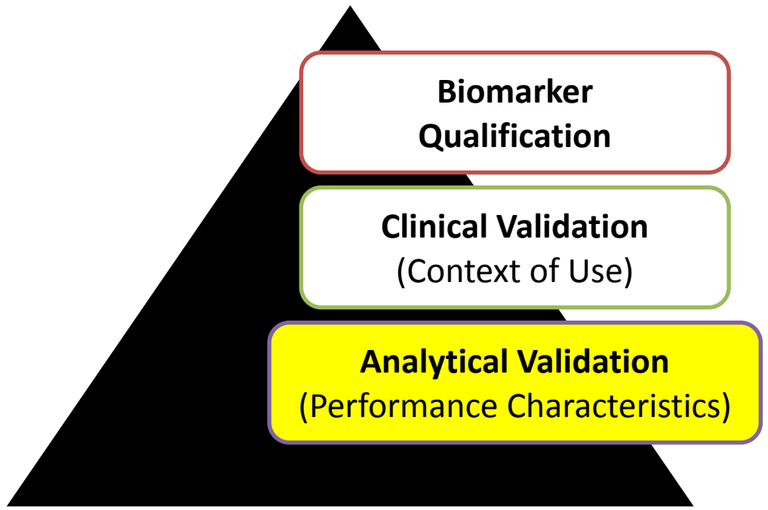


- Automatic **lesion detection** and classification
- Automatic tracking of old and **new lesion** and **its location**
- Automatic calculation of **BSI**
- Electronic Reports

1. Analytically validation

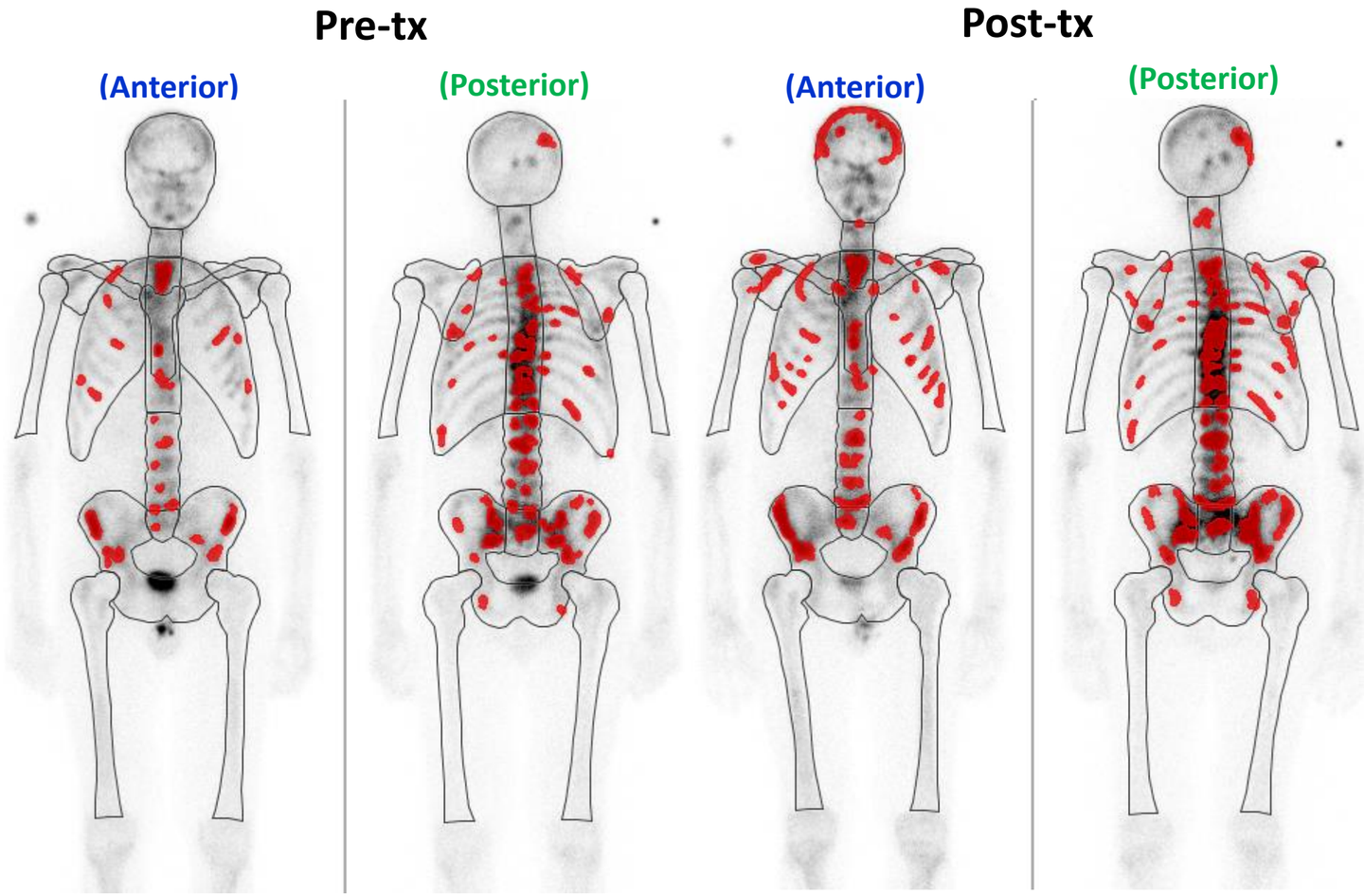


- **Reproducibility**
- **Accuracy**
- **Linearity**
- **Specificity**
- **Sensitivity**



1. Clinical Validation

Automated BSI as an analytically validated AND quantitative CLINICAL TOOL



	12/5/13	3/10/14
Bone Scan Index (%)	5.62	9.95
Number of high probability hotspots	59	73

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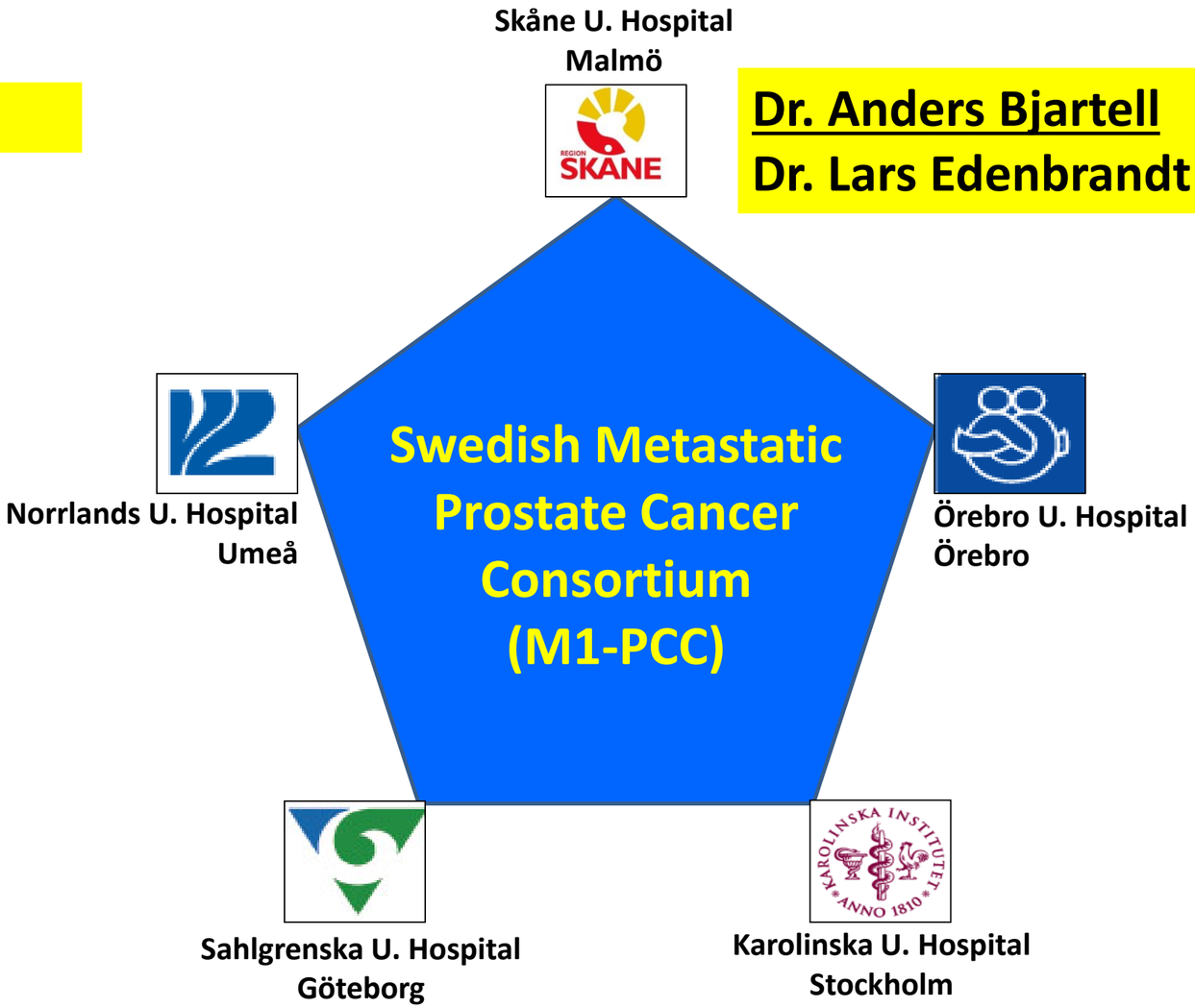

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