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Translating Prostate Cancer Working Group 2 (PCWG2) progression criteria into a quantitative response biomarker in metastatic castration-resistant prostate cancer (mCRPC).

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**Background:** PCWG2 radiographic progression criteria, which are associated with survival, rely on lesion counting. There is a need for a fully quantitative assessment of tumor burden as a component of a true response biomarker for mCRPC. Here, we used the bone scan index (BSI) to fully quantitate the increase in skeletal disease burden at each radiographic milestone that constitutes the PCWG2 criteria. **Methods:** mCRPC patients (pts) from clinical trials using PCWG2 criteria to determine progression (PD) were assessed. Pts were required to have baseline (BL) and at least two follow-up (FU) bone scans. The EXINI automated platform was used to generate BSI at key PCWG2 landmarks: 2+2 criteria for early PD and post flare PD criteria with the appearance of 1 and  $\geq 2$  new lesions. Median (M) and Interquartile range (IQR) of the relative change in BSI were calculated to quantify the increase in total tumor burden. **Results:** A total of 257 pts were assessed, of whom 169 had two or more FU bone scans at 8 or 12 week intervals. Of the total 169 pts, 86 (51%, 95%CI 43-58) met PD by PCWG criteria. 35 (41%, 95%CI 31-51) of 86 pts met the early PD criteria, the remaining 51 (59%, 95%CI 49-69) met PD at subsequent time points after flare period. The ability of the automated platform to reproduce a BSI value, retrieved from the same scan, was highly consistent (100%). The relative BSI increase during the course of meeting PD by PCWG2 is shown in the Table. **Conclusions:** This is the first quantitative assessment of changes in total tumor burden in pts meeting PCWG2 criteria. Relative changes in BSI can be substantial in meeting the criteria. These data build on the PCWG2 criteria by quantitating the increase both of existing lesions and the contribution of new lesions. We are now assessing the associations with survival that these incremental increases represent.

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PD by PCWG2 N=86 of 169	Reference scan at:	New lesion assessment at:	Median relative (%) BSI increase (IQR)
Early PD (2+2) N=35	BL	1 <sup>st</sup> FU ( $\geq 2$ new lesions)	79 (63 – 167)

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<b>PD by PCWG2 N=86 of 169</b>	<b>Reference scan at:</b>	<b>New lesion assessment at:</b>	<b>Median relative (%) BSI increase (IQR)</b>
	BL	2 <sup>nd</sup> FU ( $\geq 2 + \geq 2$ new lesions)	175 (94 – 414)
<b>Post flare PD N=51</b>	1 <sup>st</sup> FU	Appearance of 1 new lesion	38 (10 – 183)
	1 <sup>st</sup> FU	Appearance of $\geq 2$ new lesions	76 (28 – 276)
	1 <sup>st</sup> FU	Confirmation	150 (55 – 676)

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