Applying Big Data to Address the Social Determinants of Health in Oncology

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The information in this presentation does not necessarily represent the view of the FDA
Disclosures: None
Putting the Patient Back Together — Social Medicine, Network Medicine, and the Limits of Reductionism

Jeremy A. Greene, M.D., Ph.D., and Joseph Loscalzo, M.D., Ph.D.
Molecular reductionism → multiomic holism
Traditional clinical trials are exclusionary
## Immuno-oncology landscape analysis (n ~ 16,000)

<table>
<thead>
<tr>
<th></th>
<th>Immune checkpoint inhibitor (ICI) monotherapy</th>
<th>Non-ICI monotherapy (e.g., chemotherapy)</th>
<th>Dual-ICI combination therapy</th>
<th>ICI administered with non-ICI (e.g., chemotherapy)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F</td>
<td>6195 (39%)</td>
<td>972 (33%)</td>
<td>535 (33%)</td>
<td>106 (43%)</td>
</tr>
<tr>
<td>M</td>
<td>9771 (61%)</td>
<td>2006 (67%)</td>
<td>1084 (67%)</td>
<td>138 (57%)</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>60.8 (13)</td>
<td>62.2 (10.3)</td>
<td>59 (12.3)</td>
<td>60.8 (11.9)</td>
</tr>
<tr>
<td>Median (Min-Max)</td>
<td>62 (15 - 96)</td>
<td>63 (18 - 87)</td>
<td>60 (18 - 88)</td>
<td>62 (27 - 87)</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>1685 (11%)</td>
<td>273 (9%)</td>
<td>54 (3%)</td>
<td>6 (2%)</td>
</tr>
<tr>
<td>Black or African American</td>
<td>456 (3%)</td>
<td>43 (1%)</td>
<td>12 (0.7%)</td>
<td>5 (2%)</td>
</tr>
<tr>
<td>Other</td>
<td>380 (2%)</td>
<td>39 (1%)</td>
<td>33 (2%)</td>
<td>5 (2%)</td>
</tr>
<tr>
<td>White</td>
<td>13289 (83%)</td>
<td>2603 (87%)</td>
<td>1519 (94%)</td>
<td>227 (93%)</td>
</tr>
</tbody>
</table>

Immuno-oncology landscape analysis (n ~ 16,000)
New Clinical Trials Designs are Needed
Decentralized Clinical Trials

Decentralized Trials in the Age of Real-World Evidence and Inclusivity in Clinical Investigations

Scan Khozin¹ and Andrea Coravos¹,²

Decentralized clinical trials (DCTs) facilitate conducting studies outside the physical boundaries of traditional clinical research facilities. They can extend the reach of clinical investigations to historically underserved populations while enabling incorporation of tools, such as digital health and telemedicine, for high-frequency remote monitoring of patients in real-world settings. DCTs require special attention to cybersecurity and data privacy protection laws and can be an efficient means of supporting a more patient-centered and inclusive clinical research enterprise.

- Outside boundaries of traditional research facilities
- Extend reach of clinical investigations to underserved populations
- Leverage digital health solutions for data collection
Decentralized Clinical Trials
Digital Biomarkers

 npj Digital Medicine  www.nature.com/npjdigitalmed

Developing and adopting safe and effective digital biomarkers to improve patient outcomes

Andrea Coravos\(^1,2\), Sean Khozin\(^3\) and Kenneth D. Mandl\(^1,4\)

Biomarkers are physiologic, pathologic, or anatomic characteristics that are objectively measured and evaluated as an indicator of normal biologic processes, pathologic processes, or biological responses to therapeutic interventions. Recent advances in the development of mobile digitally connected technologies have led to the emergence of a new class of biomarkers measured across multiple layers of hardware and software. Quantified in ones and zeros, these “digital” biomarkers can support continuous measurements outside the physical confines of the clinical environment. The modular software–hardware combination of these products has created new opportunities for patient care and biomedical research, enabling remote monitoring and decentralized clinical trial designs. However, a systematic approach to assessing the quality and utility of digital biomarkers to ensure an appropriate balance between their safety and effectiveness is needed. This paper outlines key considerations for the development and evaluation of digital biomarkers, examining their role in clinical research and routine patient care.

*npj Digital Medicine* (2019)2:14; https://doi.org/10.1038/s41746-019-0090-4
Digital Biomarker Development
Intelligent Health (iHealth)

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Karen Boyd
Director of Research
Jessica Berrellez and Mimi Nguyen
Program Management

James Gulley, MD, PhD
NCI lead and Sponsor

Jonathan Pomeraniec, MD
NIH Clinical Researcher, Neurosurgery
Digital Biomarker Development
Intelligent Health (iHealth)

Routine
• Omics
• Imaging
• Labs
• Adverse events
• Other routine metrics

Digital
• Biosensors
• Advanced imaging
• Voice and facial recognition

Standard protocol specified analyses
AI and advanced analytics