Laboratory Informatics Approach that Drives Data Curation, Utilization and Value-add: Regulatory Compliance, Reimbursement and Monetization Strategies

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Fireside Discussion

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Pfizer Oncology
Challenges on the Diagnostic Landscape

- Laboratories generate large complex data types
- Clinical and patient histories are often in a separate system
- Gap between linking patient diagnostic information to genomic studies (phenotype & genotype) knowledge base
- Rapid advances in technology have led to a dramatic increase in the output of genomic and molecular data
- Diagnostic information is included in unstructured text
- Lack of solutions for disseminating treatment summaries that demonstrate the complexity of a diagnosis
- Reimbursement is ever more tied to clinical utility and medical necessity – requires supporting documentation for submissions and appeals
- Quality payment programs such as MACRA where physicians performance affects Medicare payments in subsequent years
Nomenclature
Nomenclature

Laboratory Informatics

Genomics
Data Aggregation
Registries
FDA
Natural Language Processing
MIPS
Utilization
CAPITATION

Real World Data

CMS vs the MACs and MolDX
NGS NCD
APM
Machine Learning and AI
Data Sharing
CMS
Risk Sharing
EKRA
PAMA

Value Based Reimbursement

Quality Reporting
Biomarkers
Integration
Reimbursement
Reimbursement

MACRA
Interoperability
Value Based Reimbursement

Registries
Reimbursement
CAPITATION
Quality Reporting
Registries
Genomics
What is Laboratory Informatics?

- Interface and Data Exchange
- Data Model and Information Architecture
- Security and Compliance
- Quality Management
Information Architecture and Data Model

PATIENTS

GENOMIC
Tumor
Germline .BA
M., .VCF, .BED
XML, PDF, TXT

IMAGING
Features/
Location,
Radiology,
Pathology,
Oncology

CLINICAL
Demographics,
Histology,
Grade, Stage,
Treatment,
Quality,
Outcomes

INTEGRATED ANALYSIS
Multi-Parametric
Analysis
Statistical Analysis
PVT Reporting
QCDR Reporting

PATIENT

CLINICAL DATA
RADIOLOGY
PATHOLOGY

DIAGNOSTIC DATA

DISCRETE GENOMIC DATA

PATIENT REPORTED OUTCOMES

DATA QC
DATABASE

DATA QC
DATABASE

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# Exponential Increase and Complexity of Lab Data

<table>
<thead>
<tr>
<th>Megabytes</th>
<th>Gigabytes</th>
<th>Terabytes</th>
<th>Petabytes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Images 500KB – 60 MB</strong></td>
<td><strong>Images &lt; 6 GB</strong></td>
<td><strong>Image &lt; 16GB</strong></td>
<td><strong>Images and Text TB</strong></td>
</tr>
<tr>
<td>Clinical imaging; clinical notes and narratives</td>
<td>Images are generated in a series; clinical reports of findings</td>
<td>High resolution Images generated from tissue samples; Multiple sources</td>
<td>Genomics NGS; and Molecular Diagnostics Extremely large data sets</td>
</tr>
<tr>
<td>Stored and managed on Files Servers</td>
<td>Stored and managed in special archives</td>
<td>Stored and managed with difficulty; live in archives and large data centers</td>
<td>High volume makes data unmanageable; large data repository and bandwidth requirements</td>
</tr>
</tbody>
</table>
Regulatory and Compliance
### Regulatory and Compliance

<table>
<thead>
<tr>
<th>CMS</th>
<th>FDA</th>
<th>CALIFORNIA CONSUMER PRIVACY ACT</th>
<th>PALMETTO GBA MoIDX</th>
</tr>
</thead>
<tbody>
<tr>
<td>• NGS NCD BRCA Testing</td>
<td>• VALID Act (Formerly DAIA)</td>
<td>• Patient/informed Consent</td>
<td>• LDT Coverage Determinations</td>
</tr>
<tr>
<td>• MACRA reporting</td>
<td>• Parallel Review based on RWE</td>
<td>• CA Consumer Privacy Law</td>
<td>• NGS NCD (hereditary) enforce CMS policy decisions</td>
</tr>
<tr>
<td>• Impact of PAMA on the CLFS</td>
<td>• Digital Health Innovation Act</td>
<td>• EKRA (formerly SUPPORT Act)</td>
<td></td>
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<tr>
<td>• Lead on Value-based Reimbursement</td>
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Reimbursement and Monetization
## Reimbursement and Monetization

<table>
<thead>
<tr>
<th>Laboratory Data</th>
<th>Pharma</th>
<th>Payers</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Clinical utility</td>
<td>• Real World Data (RWD and RWE)</td>
<td>• Real world models of utilization</td>
</tr>
<tr>
<td>• Quality reporting/regulatory reporting</td>
<td>• Clinical Trials</td>
<td>• Patient population cohorts</td>
</tr>
<tr>
<td>• Appeals and adjudication</td>
<td>• Genomic and biomarker landscape overview</td>
<td>• Patient support and engagement</td>
</tr>
<tr>
<td>• Registries (data quality)</td>
<td>• Patient education</td>
<td>• Clinical utility in large and small populations</td>
</tr>
<tr>
<td>• Used for contract negotiation</td>
<td>• R&amp;D and discovery</td>
<td>• Organized data equals value</td>
</tr>
<tr>
<td>• Value-based payment (incentives in contracting)</td>
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</tbody>
</table>
What to Expect – Predictions from Silicon Valley

- Payer consolidation – Bigger payers have narrower networks favoring national labs
- Physician-led ACOs – great opportunity for labs to deliver rich data and analytical services creating opportunities for contracting
- Interoperability becomes more of a standard - Labs (and their data) will need to adopt mechanisms for data exchange with EMRs
- Billing and reimbursement will be scrutinized – end of up coding
- Introduction of new sequencing technologies (NGS) – drive competition forcing labs to develop biomarker strategies with physicians
- The explosion and ability to link clinical, diagnostic and financial data will continue to grow making data monetization a reality

Data Aggregation and Curation – Documentation

Improve Reimbursement
Submit clinical notes with appeals
• Establish medical necessity
• Demonstrate how results were used to guide treatment

MACRA/MIPS reporting
• Develop quality metrics reports
• Document healthcare team collaboration & clinical improvement activities

Improve Payor Coverage
Leverage patient data pool
• Establish clinical utility - coverage
• Curation of real world data for predictive modeling in diagnostics

Develop New Revenue Streams
Repurpose aggregated patient data sets
• Reuse data for research and drug discovery
• Develop patient profiles
• Package data for commercial development in pharma
Intersection of Data Sharing, Regulatory Compliance, and Reimbursement

Oncologists Identify Qualified patients & Risk Factors

Registry Enrollment, Demography, Risk Factors, Initial Evaluation, Clinical Notes

Ongoing Treatments, Intermediate Outcomes & NGS Tests to determine Companion Diagnostics

Outcomes, Final Disposition

Quality Assurance
FDA
Research
Pharma
Payors
Stakeholders

Laboratories

- Improve quality performance and reimbursement using real-time reporting of quality measures
- Obtain insights into best practices by mining de-identified data for similar patient cohorts
- Short term: Leverage patient data to support and streamline reimbursement appeals
- Long Term: Develop real world evidence (RWE) to establish clinical utility (CU) for diagnostic test coverage

Physician and Cancer Practice

- Improve quality of oncology patient care
- Support educational and business needs of oncology practitioners
- Promote research using real world data (RWD) to broaden applicability to diverse populations and settings

Payors

- Evidence Development registry as a path toward value-based care (CED but likely without Coverage)
- Streamline claims processing with “pre-approved” diagnostic tests and/or vendors

Pharma

- Expanded drug indications
- RWD: Drug effectiveness and safety / adverse events
- Disease insights
- Population health outcomes
The Impact of Quality Laboratory Data on Healthcare

- The challenge of positioning your test as the best in class
- Opportunities for sole source labs with distinguished menus and educated sales team
- Dependent on highly evolved data capabilities (interoperability) for data exchange
- Targeted message to physicians as KOLs and C-suite
- Integrate into the process for meeting quality standards and reporting (OCM)
- Provide data sharing and bidirectional flow of data (interoperable) with practices and hospitals
Summary

- Investment in IT/Informatics infrastructure remains a primary initiative for laboratories to maintain and continuously improve operations and remain competitive.
- Data driven approach links to other lab operations and efficiencies, establishes a path to clinical utility, appeals and payor negotiations.
- Data aggregates have value in cancer outcomes and drug development and can be viewed as a new line of business.
- Informatics and the IT infrastructure necessary to facilitate collaboration with ordering physicians provides the opportunity to engage physicians in the ordering process through collaboration frameworks such as tumor board.
- Adoption of IT and a laboratory informatics approach to actively participate in the healthcare landscape makes the laboratory sticky with their partner health systems.
Thank You
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