Oncoclínicas

CodeX meeting

Rodrigo Dienstmann
Medical Director, Oncoclínicas Precision Medicine
• High level overview of Oncoclínicas
• Oncoclínicas Precision Medicine and Big Data Initiative
• mCODE implementation in Big Data platform and enterprise-wide EMR system
• Current and future use cases
70 clinics + 2 comprehensive cancer centers in 32 cities in Brazil + Bioinformatics Lab in the USA
ONCOCLÍNICAS FACTSHEET 2020

- **70 +** Clinics in 32 cities
- **> 1.000** Physicians
- **160 k** Patients Seen
- **64 k** new
- **42 k** Patients Treated
- **16 k** new
- **19 k** Metastatic Patients Treated
- **9 k** new
- **350 k** Treatment cycles

**Sex**
- Male 30%
- Female 70%

**Age**

<table>
<thead>
<tr>
<th>Years</th>
<th>0-14</th>
<th>15-29</th>
<th>30-39</th>
<th>40-49</th>
<th>50-59</th>
<th>60-69</th>
<th>70-79</th>
<th>80+</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td>1</td>
<td>5</td>
<td>11</td>
<td>15</td>
<td>17</td>
<td>21</td>
<td>19</td>
<td>12</td>
</tr>
</tbody>
</table>

**Tumor**

- Breast 19%
- Prostate 37%
- Hematological 6%
- Colorectal 8%
- Lung 11%
- Pancreas 17%
- Others 2%

Source: Oncolínicas database and analysis
TREATMENT SERVICES OFFERINGS

Systemic therapy

Radiotherapy

Expansion of Treatment Services

Cancer Centers

Surgery

Clinical Studies

Pathology Genomics

BMT – Cell T
ONCOCLÍNICAS ONCOLOGY DRUGS AND CLINICAL TRIALS

DEMOGRAPHICS AND CARE PATHWAYS

✓ Diverse population
✓ Private health insurance setting
✓ Consistent practice and prescribing patterns

EARLY ACCESS TO STANDARD-OF-CARE THERAPIES

✓ 95% of USA and EU approved drugs available in Brazil
✓ Average 6 months time lag between FDA and local (ANVISA) drug approvals in recent years

COMPREHENSIVE CLINICAL TRIAL PORTFOLIO

✓ Largest network for clinical research in private setting
✓ 40% increase in number of active studies/year over the last 3 years

CLINICAL TRIALS (FEB 2021)

- Active studies: 117
- Global regulatory trials: 88
- Molecular-driven trials: 37
OUTLINE

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• mCODE implementation in Big Data platform and enterprise-wide EMR system
• Current and future use cases
ONCOCLÍNICAS PRECISION MEDICINE DRIVERS

Need for **high-quality pathology** to optimize sample selection and preparation for efficient molecular diagnostics

- Centralized Pathology Lab
- Pathologist education

Need to implement molecular testing with a **streamlined process to maximize impact**

- EMR with molecular journeys and clinical pathways
- In-house “one-stop-shop” solution

Need to **facilitate clinical decision-making** to increase molecularly-guided treatment opportunities

- Oncologist education
- Customized NGS reports + hotline

Oncoclínicas Pathology + NGS + EMR data = **Unprecedented resource** for biomarker discovery and pharma **collaboration**

- Real-world data reports with clinical experts
- We are uniquely positioned in LatAm, real-life community oncology practice
Full building dedicated to **Anatomic Pathology, Genomics and Big Data Laboratories** with 25,000 square feet;

Central laboratory for pathology slide review with high automation, including **DIGITAL PATHOLOGY** and usage of artificial intelligence algorithms;

Complete molecular diagnostics workflow integration, from standard diagnostics to NGS panels;

High adaptability for new test validation;

Dedicated data analytics team in the same location.

**Accreditation**

**Proficiency Tests**
ONCOCLÍNICAS PRACTICES MEDICINE AT HIGHEST STANDARDS

Key strategic partnerships

- **Dana-Farber Cancer Institute**
  - Pathways, Tumor Boards, Medical & Pharmacy Training

- **Massachusetts General Hospital - Boston Lighthouse**
  - Molecular Pathology and Bioinformatics

- **ARCHER™**
  - DNA and RNA assays for tumor NGS

- **PAIGE**
  - Digital Pathology + Artificial Intelligence algorithms

BEAT CANCER
• High level overview of Oncoclínicas

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BIG DATA IN HEALTHCARE

Data Rationalization
- Electronic Medical Record (EMR)
- Companion diagnostics

Data Enrichment
- Next-gen EMR
- Genomics
- Digital Pathology
- Imaging
- Mobile health
- Patient reported outcomes

Data Insights
- Biomarker discoveries
- Decision support systems
- AI-powered products
- Regulation and contracting

Descriptive
- Infrastructure
- Audit
- Cleansing
- Standardization

Diagnostic
- Integration
- Wrangling

Predictive & Prescriptive
- Analytics
- Optimization

Integrity

Reputation (research-grade)

Intelligence (regulatory-grade)

Business decisions

Care & Research decisions
ONCOCLÍNICAS BIG DATA INFRASTRUCTURE AND GOVERNANCE

1. Pre-Qualification
   - Raw Data
   - Pseudonymization process
   - Data quality check
     (cleansing, matching, and standardization)

2. Curation
   - Stage 1 (Pre-Qualified)
   - Curation process
   - Data Enrichment (external sources)
   - Natural Language Processing

3. Exploration
   - Stage 2 (Curated)
   - Anonymization process
   - Production
     - SQL
   - Biostatistical analysis
     - Clinical concepts and attributes
   - Clinical data access

(*) Non personally identifiable information
(non-PII) *

+BEAT CANCER+
Structured longitudinal data acquisition at the source + manual curation

ONCOCLÍNICAS REAL WORLD DATA

CURATION ON LEGACY EMRs

Structured / Mandatory fields

Need to be curated

ENTERPRISE-WIDE CUSTOMIZED
ONCOLOGY-FOCUSED NEXT-GEN EMR

Proportion of patients with complete data in Next-Gen EMR

Unique opportunity to promote mCODE adoption and capture data of higher quality at the source.
QUALITY METRICS – BEFORE CURATION

Staging at baseline

- Em Estadia: 268, 1.1%
- N/A: 187, 0.7%
- I: 2.826, 11.1%
- II: 3.701, 14.5%
- III: 3.790, 14.9%
- IV: 5.793, 22.7%
- Não preenchido: 8.936, 35.0%

75% of patients with solid tumors starting therapy did not have information of staging at baseline.
Treatment line metastatic setting

70% of active patients receiving in metastatic setting did not have information treatment line.
QUALITY METRICS – BEFORE CURATION

Death date

60% of inactive patients (without follow-up visits) in last 1 year did not have death date registered.
QUALITY METRICS – BEFORE AND AFTER CURATION

**SUMMARY**

<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>Total Patients</th>
<th>Curated Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast</td>
<td>10,478</td>
<td>1,922</td>
</tr>
<tr>
<td>Colorectal</td>
<td>3,000</td>
<td>1,078</td>
</tr>
<tr>
<td>Kidney</td>
<td>2,132</td>
<td>269</td>
</tr>
<tr>
<td>Lung</td>
<td>2,812</td>
<td>1,269</td>
</tr>
<tr>
<td>Melanoma</td>
<td>344</td>
<td>238</td>
</tr>
</tbody>
</table>

*All curated patients have metastatic behavior, either at the staging time or a progression to metastasis.*

**Overall Survival**

Considering only curated patients

- OS before curation
- OS after curation
- OS metastatic after curation

Deaths are not registered on the correct structured fields on EMR. This causes a wrong OS curve, as if we didn’t have many deaths.

On EMRs we don’t have registered the metastatic diagnosis data on structured fields.
ONCOCLÍNICAS REAL WORLD DATA

Structured longitudinal data acquisition at the source + manual curation

CURATION ON LEGACY EMRs

Structured / Mandatory fields

Need to be curated

$$mCODE^*$$

CURATION ON ENTERPRISE-WIDE NEXT-GEN EMR

Structured / Mandatory fields

$$mCODE^*$$

Need to be curated

$$mCODE^*$$
<table>
<thead>
<tr>
<th>Status</th>
<th>Atendimento</th>
<th>Data da avaliação</th>
<th>Profissional</th>
<th>ECOG</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1553</td>
<td>06/04/2020 17:55:31</td>
<td></td>
<td>0 - Completamente ativo e capaz de realizar sem restrição</td>
</tr>
</tbody>
</table>
BEAT CANCER

mCODE – v1.0

This illustration is not a formal part of the mCODE specification. Names and structural relationships shown here may not precisely correspond to the data dictionary and FHIR profiles.
Diagnóstico do tumor

Data do registro: 16/07/20

Médico:

Código ICD 10: C50
Nome: Neoplasia maligna da mama

Opções:
- Cuidado continuado
- Diagnóstico inicial
- Localmente avançada
- Metástase
- Rastreamento
- Recidiva
- Recidiva/Metástase
- Segmento clínico
### Protocolos

<table>
<thead>
<tr>
<th>Modalidade/linha</th>
<th>Protocolo</th>
</tr>
</thead>
<tbody>
<tr>
<td>1ª - Linha</td>
<td>Mama Neo/Adjuvante</td>
</tr>
<tr>
<td>2ª - Linha</td>
<td></td>
</tr>
<tr>
<td>3ª - Linha</td>
<td></td>
</tr>
<tr>
<td>4ª - Linha</td>
<td></td>
</tr>
</tbody>
</table>
mCODE – v1.0

This illustration is not a formal part of the mCODE specification. Names and structural relationships shown here may not precisely correspond to the data dictionary and PHIR profiles.
## mCODE – v1.0

### Desfecho

<table>
<thead>
<tr>
<th>Desfecho</th>
<th>Sem evidência de doença</th>
<th>Com evidência de doença</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sem evidência de doença</td>
<td>---</td>
<td>---</td>
<td><strong>DD/MM/YYYY</strong></td>
</tr>
</tbody>
</table>

**Qual serviço?**

- Em tratamento
- Em seguimento

**Outros**

Liberar template
Desfecho

Com evidência de doença

Em tratamento com resposta / Benefício clínico;
Em tratamento com doença estável;
Em tratamento com progressão da doença;
Em suporte com cuidados continuados;
ONCOCLÍNICAS mCODE ADOPTION

PHYSICIAN TRAINING

- Real World Data
- KOLs promoting internal research
- Mindset change

- Video tutorials during site kick-off new EMR
- Keep site personnel engaged in the Big Data Project
- Quality metrics

PHYSICIAN COMPENSATION AND ENGAGEMENT

Financial (15%)
- Treatment margin

Peer development (15%)
- Mentorship, performance

Commitment (15%)
- Internal/external engagement
- Training, self-development

Quality (20%)
- Compliance, adherence to processes
- Participation in boards
- EMR completion
- Patient satisfaction

Utilization (35%)
- First and follow-up visits
- Cross-referrals
- Exclusivity

Proportion monthly payments
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ONCOCLÍNICAS REAL WORLD DATA INSIGHTS

COLLABORATIONS

ACCESS TO INSIGHTS

RESEARCH

DRUG/TECHNOLOGY TRACK

- Product utilization, value and safety
- Comparative effectiveness
- Pharmacovigilance
- Innovative contracts

TRIAL TRACK

- Feasibility analysis with intelligent trial design
- Streamlined clinical trial recruitment
- Natural history cohorts
- Synthetic controls arms
ONCOCLÍNICAS 200K CURATED ONCOLOGY POPULATION YEAR-END 2022

Estimated new patients 2021 +
new uploads in Data Lake

Total year-end 2021

Estimated new patients 2022

Total year-end 2022

(numbers in '000)

<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>Breast</th>
<th>Prostate</th>
<th>Colorectal</th>
<th>Lung</th>
<th>Non-Hodgkin Lymphoma</th>
<th>Multiple Myeloma</th>
<th>Others</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retrospective Data Lake</td>
<td>18.6</td>
<td>5.8</td>
<td>28.1</td>
<td>14.6</td>
<td>5.2</td>
<td>2.7</td>
<td>42.7</td>
</tr>
<tr>
<td>Estimated new patients 2021</td>
<td>46.8</td>
<td>12.2</td>
<td>13.0</td>
<td>6.3</td>
<td>3.5</td>
<td>2.8</td>
<td>15.2</td>
</tr>
<tr>
<td>Total year-end 2021</td>
<td>59.8</td>
<td>15.7</td>
<td>11.8</td>
<td>6.1</td>
<td>4.4</td>
<td>74.4</td>
<td></td>
</tr>
<tr>
<td>Total year-end 2022</td>
<td>59.8</td>
<td>27.8</td>
<td>15.7</td>
<td>11.8</td>
<td>6.1</td>
<td>4.4</td>
<td>74.4</td>
</tr>
</tbody>
</table>
ONCOCLÍNICAS LUNG CANCER RWD COMPARED TO FLATIRON
Clinico-genomics cohorts – identifying unmet medical needs

BEAT CANCER

EGFR, ALK, ROS1 and BRAF

19.1 months

Real World Data

TKI: tyrosine kinase inhibitor

Singal et al, JAMA 2020
**ONCOCLÍNICAS MELANOMA RWD COMPARED TO TRIAL**

Effectiveness in real practice – validate results of trials, understand real-world patterns

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**Nivolumab + Ipilimumab**

1\(^{st}\) line: 65%

2\(^{nd}\) line: 25%

3\(^{rd}\) line: 10%

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52% alive at 36 months

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**Clinical Trial Data Checkmate-067**

Nivolumab + Ipilimumab

1\(^{st}\) line: 100%

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58% alive at 36 months

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Larkin et al, NEJM 2019
CheckMate 7DX
NCT04100018

Patients with prostate cancer from data lake → 7,221
Androgen deprivation or orchiectomy → 4,259
Patients with abiraterone or enzalutamide → 991
Metastatic patients → 658
Patients without docetaxel treatment → 486
Active patients in the last 6 months → 269
Active patients in the last 3 months → 212
GOC Botafogo clinic → 23
DISCUSSION

- mCODE simplified process of data curation and EMR design
- Opened door to research and pharma collaborations on real world data

FUTURE STEPS

- Quality metrics after new EMR implementation: completeness, conformance, plausability
- Incorporate mCODE updates
- CODEx