Jon Mangion
1st July 2019

Ion Torrent - Best practices in NGS data collection, management and analysis
Our Impact: Ion Torrent NGS Systems

>600 tests implemented in clinical research labs

Hundreds of thousands of test results generated in clinical research labs

>3,300 total publications
>100 peer-reviewed clinical oncology research publications
Ion GeneStudio™ S5 System

Immuno-oncology Solutions

FFPE Based Solutions

Heme Oncology Solutions

Liquid Biopsy Solutions

End-to-End Oncology Solution
Ion AmpliSeq Technology Empowers Targeted Sequencing

Ion AmpliSeq™ technology

Gene panels or exomes
As low as 1 ng DNA and RNA
Transcriptome and gene expression
Gene fusions
SNPs, indels, CNVs
Single-tube workflow

For Research Use Only. Not for use in diagnostic procedures.
Superior Performance Across NGS Technologies

Astra Zeneca ESMO publication
ESMO Open 2017;2:e000235. doi:10.1136/esmoopen-2017-000235

Key differences between 13 KRAS mutation detection technologies and their relevance for clinical practice

James L Sherwood, Helen Brown, Alessandro Rettino, Amelie Schreieck, Graeme Clark, Bart Claes, Bhuwnesh Agrawal, Ria Chaston, Benjamin S G Kong, Paul Choppa, Anders O H Nygren, Ina L Deras, Alexander Kohlmann

1Personalised Healthcare and Biomarkers, AstraZeneca, Cambridge, UK; 2West Midlands Regional Genetics Laboratory, Birmingham, UK; 3IMGM Laboratories GmbH, Martinsried, Germany; 4Department of Medical Genetics, University of Cambridge, Cambridge, UK; 5Biocartis NV, Mechelen, Belgium; 6Vela Diagnostics, Singapore; 7NewGene Ltd, Newcastle upon Tyne, UK; 8Thermo Fisher Scientific, West Sacramento, CA.

Source: http://esmoopen.bmj.com/content/2/4/e000235
License: https://creativecommons.org/licenses/by/4.0/
No changes were made.
Assay Validation Readiness

- Specifically selected and expertly assessed oncology controls bring increased value to your customer
- Assessment reports to help instil immediate confidence in the performance of our Oncomine assays
- Service fully supported by our Field and Global teams
- Connect your customer to our global compliance experts
- Clarify your customer’s path to accreditation, bring workflows online more quickly, for less cost and kick start consumable pull through.
AV Consulting Services for NGS Panels—Timeline: 3 Months Vs. 9 Months

<table>
<thead>
<tr>
<th>~2 weeks</th>
<th>~3 weeks</th>
<th>~1 week</th>
<th>~6 weeks</th>
<th>1-2 weeks</th>
<th>~1 week</th>
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</thead>
</table>

**Project planning**
- Customer chooses assay and places order
- FSE, FAS, PM, CAC assigned
- Project plan prepared with timelines

**Instrument qualification and training**
- Instruments calibrated and qualified by FSE
- FSE provides basic instrument operation training
- FAS provides instrument training
- CAC provides application training and validation support

**Pre-validation planning**
- Determine targets, acceptance criteria, and bounds
- Procure well-characterized samples and controls
- Preliminary validation plan and draft protocols

**Validation testing conducted by the lab**
- Final validation plan template, protocol templates, and experiment design
- Weekly monitoring of runs with data analysis
- Hands-on workflow training

**Analysis and validation report**
- Conduct data analysis review
- Review results of analysis
- Draft validation report template and review

**AV consulting completion**
- Final validation report template
- Final doc review
- Project sign-off

**Test enablement (post-AV)**
- May be required:
  - Additional validation requirements
  - Accreditation
  - Reporting

Legend:
- **Off-site**
- **On-site**
- Available through partners
- Observed common pitfalls for labs that do not use our service
- Comes with instrument purchase
  - Managed through the AV Consulting Service

On average, we help labs complete their validation process 62% faster than on their own.
### Oncomine Informatics Workflow

**Remove barriers to NGS analysis and focus on finding meaningful results**

<table>
<thead>
<tr>
<th>What is it?</th>
<th>What it does</th>
<th>Benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sequencing analysis</strong></td>
<td>Raw data analysis, alignment, and variant calling</td>
<td>Fast, accurate, and consistent analysis optimized for Ion sequencing</td>
</tr>
<tr>
<td><strong>Annotate and filter</strong></td>
<td>Identifies copy number variants and fusions, and annotates cancer drivers</td>
<td>Identify likely driver variants, reducing calls from hundreds to a few</td>
</tr>
<tr>
<td><strong>Create custom reports</strong></td>
<td>Link variants to relevant, published evidence</td>
<td>Quickly create custom, lab-generated reports</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Data journey</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sequencing reads to BAM file</strong></td>
<td><strong>BAM file to VCF file</strong></td>
</tr>
</tbody>
</table>

**Torrent Suite Software**

**Ion Reporter Software with Oncomine plugin**

**Oncomine Knowledgebase Reporter**

**Design and manufacturing**

**Oncomine Knowledgebase Reporter**

**Sequence analysis**

**Oncomine Knowledgebase Reporter**
Summarize Your Data in Single Page Customizable Report

Example report from the Oncomine Knowledgebase Reporter

- Customizable headers, footers, sections
- Index / Report Highlights
- Variant Summary includes targeted therapies on 1st page
Traditional Data Management Solutions

Data is Managed Vertically

Data is Used Horizontally

Researcher/clinician ➢ IT needs

Regulators / Compliance ➢ Analytics / Sharing

➢ Regulation and audit rule conflict ➢ Limited consistency - silos ‘behaves’ differently ➢ Retrieval is forensics exercise
A New Approach to Long-Term Data Management

- Vertical / Silo → Integrated / Unified
- Closed / Monolithic → Open & Modular
- Manual / Reactive → Automated & Proactive

- Cross enterprise data management
- Focus on needs, not data source
- Reduce vendor dependency
- Industry adopted open source
- Automating mundane tasks
- Enhance governance, reduce costs
Arkivum TRUST - an Integrated Approach to Life Sciences Data

Example - Compliant Regulated Life Science Organization

➢ Control

➢ Compliance

➢ Cost
Arkivum Trust Benefits

- Proactive (raw) data management
- Protects data integrity
- Ensures long term readability
- Metadata capture
- Flexible data model
- Allows secure data sharing
- Compliant – GDPR and ALCOA-C
- Conforms to F.A.I.R standards: Data is Findable, Accessible, Interoperable and Reusable
- Integration with Ion Systems
- Thermo Fisher Partner

PRESS RELEASE

Oncologica, a Leading CRO, Selects Arkivum for Integrated Long-Term Data Management of Next-Generation Sequencing Data
Oncomine Solution is the Complete Answer for Oncology

Intelligently developed and integrated from sample to result

**Oncomine™ Assays**
- FFPE tissue
- Liquid biopsy
- Immuno-Oncology
- Heme-Oncology

**Assay Technologies**
- Ion AmpliSeq™ technology
- Applied Biosystems™ MagMAX™ cfNA technology

**Verified Protocols for Clinical Research**
- Relevant
- Robust
- Reproducible

**Implementation Support**
- Clinical Application Consultants

**Sequencing Technologies**
- Ion GeneStudio™ S5 Systems
- Ion Chef™ Instrument

**Oncology Research Informatics**
- Oncomine™ Knowledgebase Reporter
- Ion Reporter™ Software

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