

Integrated report using the Ion Reporter and Oncomine™ Reporter

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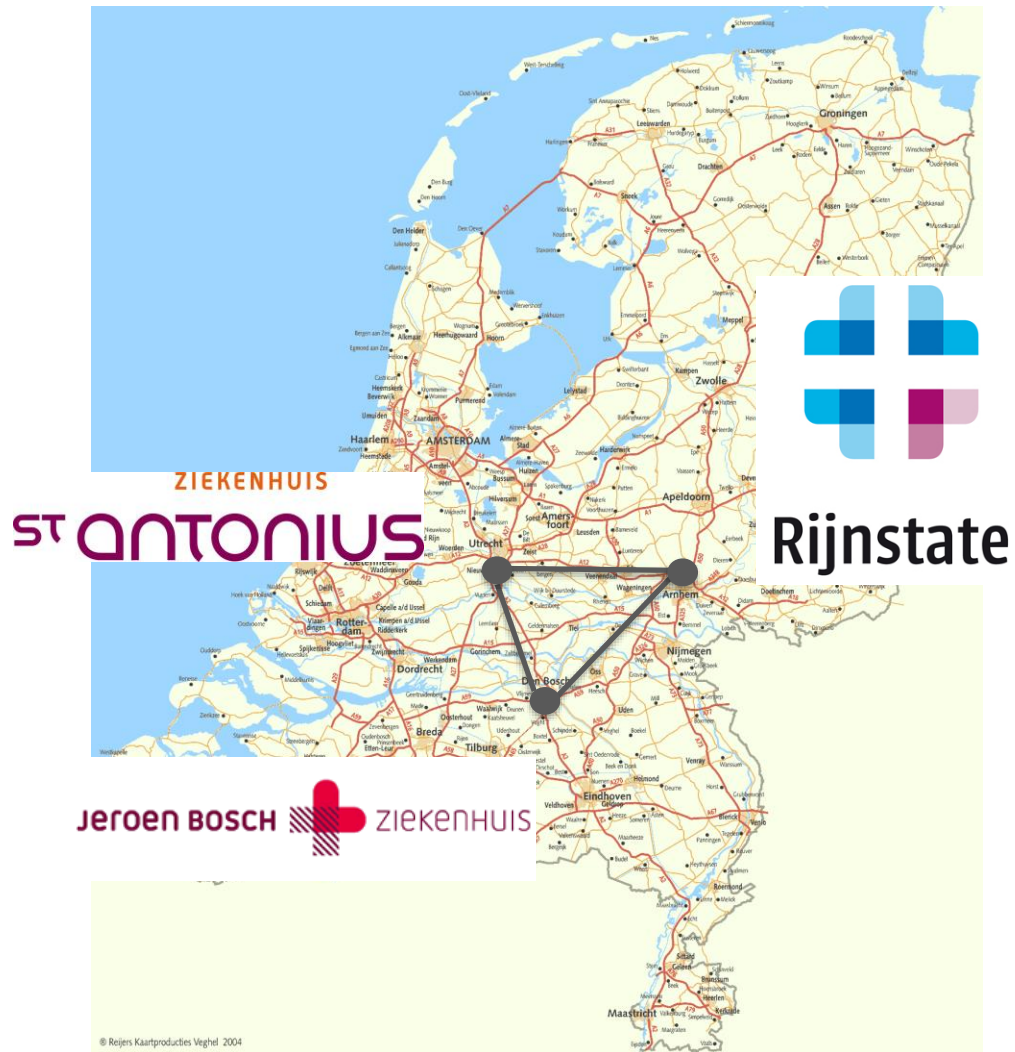
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Outline

- Pathologie-DNA
- Mutation detection in centralized NGS-facility
- PGM vs. S5 workflow
- Oncomine Reporter
- Preliminary results/Cases
- Conclusions

Pathologie-DNA



Mutation detection in centralized NGS-facility

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- Order
- Tissue cutting etc.
- Transport to centralized Pathologie-DNA NGS facility, loc. AZN



- Reporting to local LIMS using ICT

Ion PGM™ vs Ion GeneStudio™ S5 Prime



Dependent on Chip:

- 0,4M-5,5M reads
- 0,1-2 Gigabases

Panels:

- OST (22 genes)
- CHPv2 (50 genes)
- RNA fusion (3 genes)



Dependent on Chip:

- 2M-130M reads
- 0,3-50 Gigabases

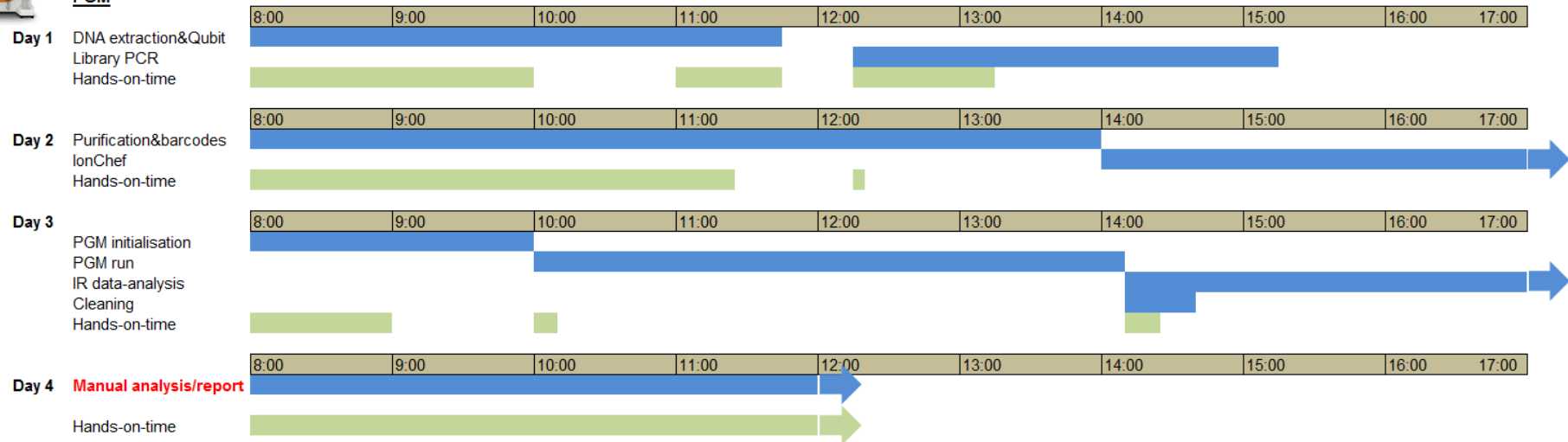
Panels:

- OST panel (22 genes)
- CHPv2 panel (50 genes)
- RNA fusion (3 genes)
- Focus (35 genes, 19 CNV, 23 fusion genes)
- Comprehensive (86 genes, 48 full length genes, 47 CNV, 51 fusion genes)
- Tumor mutational burden (409 genes)
- Liquid biopsy cfDNA Lung (11 genes)

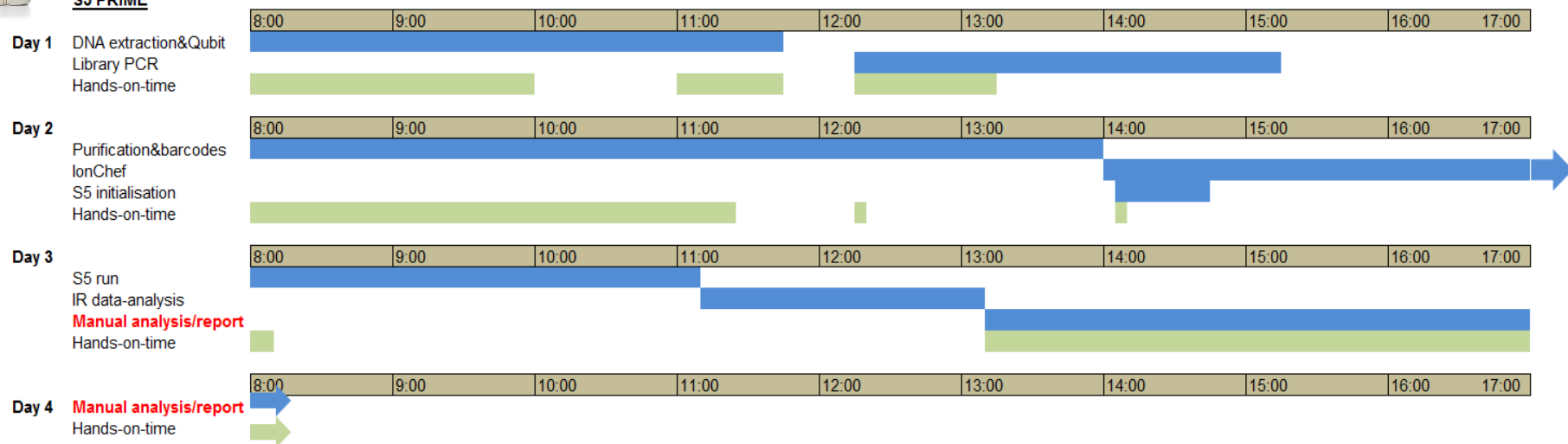
PGM vs S5 PRIME: OST workflow



PGM



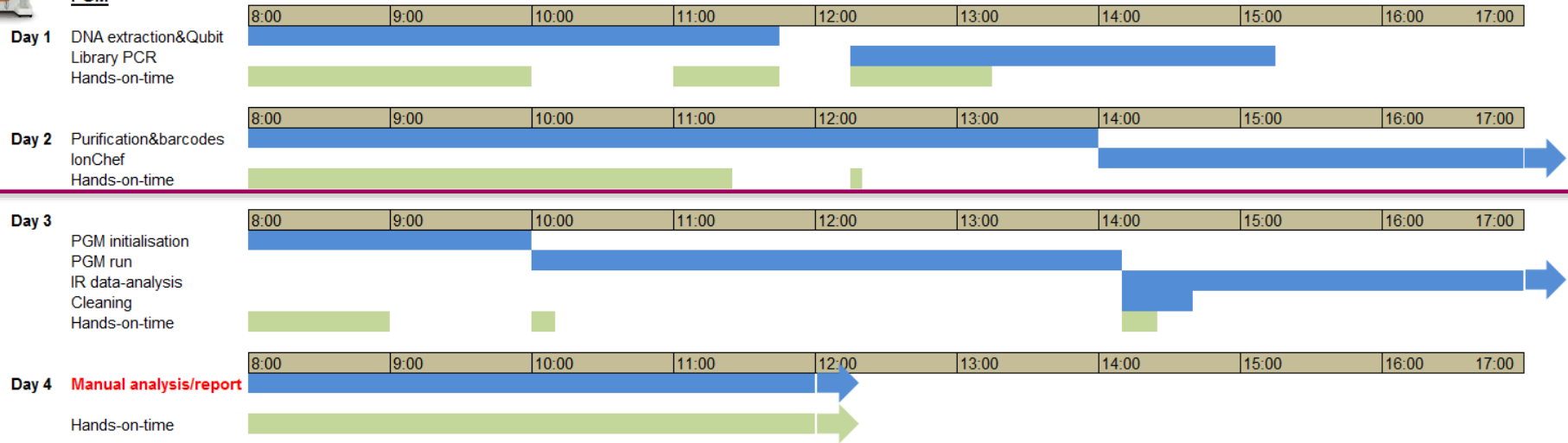
S5 PRIME



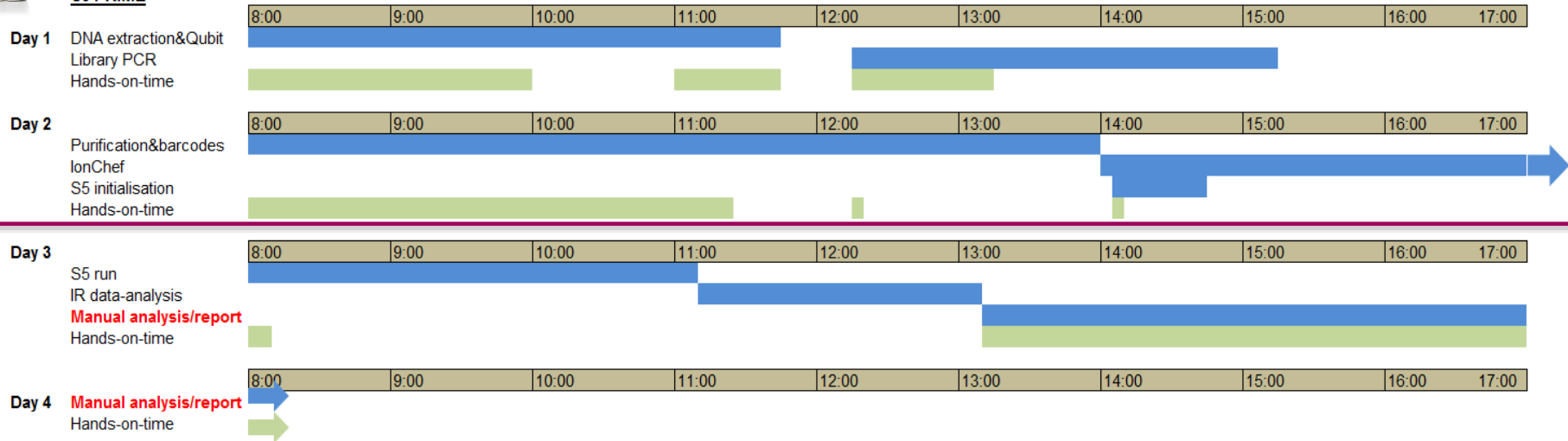
PGM vs S5 PRIME: OST workflow



PGM



S5 PRIME



PGM vs S5 PRIME

- Impact of S5 PRIME vs PGM
 - Reduction of hands-on time (~1.5 hours)
 - Reduction of time-to-result (≥ 0.5 day)
 - Increased ease of use (cartridge-based RFID tagged reagents)
 - Increased sequencing capacity; higher number of samples and more complex panels (influences time-to-result)

Oncomine™ Reporter

- Increased sequencing capacity/more complex panels
 - Need for systematic mutation calling and classification
 - Preference for software package that does interpretation
 - Standardized
 - Up-to-date
 - Easy to use
- Oncomine™ Reporter: selection of 11 cases
 - Combination of different (hotspot) mutations
 - Non-hotspot mutations (e.g. non-V600 BRAF)

Oncomine™ Reporter Content & Curation



Slide courtesy of Thermo Fischer Scientific

Oncomine™ Reporter Content & Curation

Content

Two key forms of relevant content across 42 cancer types

Clinical consensus*

- Clinical consensus information provided for research is reflected from published, approved therapies, and current treatment guidelines based on genetic event status
- Collected from US and European sources: FDA, NCCN™, ESMO, EMA

Global clinical trials

- Global clinical trials with open enrollment in which genetic events are used as enrollment criteria
- Collected from public and private data sources, including clinicaltrials.gov

* Clinical consensus:

For Ion Torrent™ Oncomine™ Reporter, clinical consensus content is defined as information on published and approved therapies, and current treatment guidelines based on genetic event status put forth by a governmental or other medical, clinical, or physician-accepted authority, such as the FDA, NCCN™, ESMO, and EMA.

- **Quality content:** Meticulously curated data, updated quarterly



Curation

Two-reviewer process

- Each piece of candidate evidence is manually curated and standardized by multiple independent reviewers for context, categorization, and concordance
- The process helps ensure that the data are comparable where there are differing reporting standards from global sources
- A team of data managers, cancer biologists, systems engineers, and biostatisticians carefully guide the data through this meticulous data collection and curation workflow

Slide courtesy of Thermo Fischer Scientific

Oncomine™ Reporter: workflow

- Uses Ion Reporter VCF files
- Upload on website ThermoFisher
- Create new case
- Analyse
- Generate report

OncoPrint™ Reporter: home screen

The screenshot shows the OncoPrint Reporter web application interface. The browser window has a single tab titled 'OncoPrint Reporter' and the address bar shows the URL 'https://apps.thermofisher.com/apps/okr/index.html/'. The application header includes a hamburger menu icon, the text 'OncoPrint Reporter', and user information (a red '19' badge, a globe icon for 'US', and a user profile icon). The main navigation bar contains links for 'Home', 'Analyses', 'Batch Analyses', 'Settings', 'Preferences', and 'Available Credits: 5'. A left sidebar contains icons for home, folder, grid, document, people, and a more options menu. The main content area is divided into three sections: 'Quick links to get started' with buttons for 'Generate Report' (Create analysis, View analyses) and 'Run Batch Analysis' (Create batch analysis, View batch analyses); 'Have questions?' with a link to 'Online Help'; and 'What's new in OncoPrint Reporter 4.4' which lists content upgrades and report usability improvements.

OncoPrint Reporter

Home Analyses Batch Analyses Settings Preferences Available Credits: 5

Quick links to get started

Generate Report

Create analysis View analyses

Run Batch Analysis

Create batch analysis View batch analyses

Have questions?

Please see the [Online Help](#) for help.

What's new in OncoPrint Reporter 4.4

Content upgrades

- New and updated biomarker descriptions, including genes important in Myeloid Cancer
- New hematological cancer types including B-cell lymphoma subtypes
- Evidence for microsatellite instability (MSI) and stability (MSS) status
- New and updated data from clinical trials as well as labels and guidelines from the US and Europe

Report and usability improvements

- **Report Template Builder:** Optimized workflow by consolidating custom sections in a single tab
- **Variant Details Table:** Improved ability to customize column selections

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Software Version: v 4.4.0 r 9f9251c | Data Version: 2019 09(005)
DISCLAIMER: The data presented here is a result of the curation of published data sources, but may not be exhaustive.

OncoPrint™ Reporter: create new case

The screenshot shows the 'Create Analysis' page of the OncoPrint Reporter application. The browser address bar shows the URL: <https://apps.thermofisher.com/apps/okr/index.html#/analysis>. The application header includes a navigation menu with icons for Home, Analyses, Batch Analyses, Settings, and Preferences, along with a user profile icon and 'Available Credits: 5'. The main content area is titled 'Create Analysis' and contains the following sections:

- File Source ***: Radio buttons for 'DataConnect' (selected) and 'My Computer'. Below is a text description: 'Specify the source of the file(s) containing genomic variants. This can be either a local drive or DataConnect.'
- Genomic Variants File(s) ***: A text description: 'Specify the file(s) containing the genomic variants on which to report. Each file may be a Variant Call Format (.vcf) file, a .zip file containing variants, a .txt file containing chromosomal alterations, or an image file to include in the report.' Below is a blue button labeled 'Select File(s)' with a file upload icon.
- Analysis Name ***: A text input field with the placeholder 'Name'. Below is a text description: 'Specify a name for the analysis.'
- Filter Preset ***: A dropdown menu with 'Filter trials NL' selected. Below is a text description: 'The Filter Preset determines what evidence is included on the report. Filter settings may be changed prior to generating the report.'
- Assay**: A dropdown menu with 'OncoPrint Solid Tumour Panel' selected. Below is a text description: 'Specify the Assay used to indicate genes assayed.'

At the bottom right, there are three buttons: 'Return', 'Reset', and 'Upload & Review Content' (disabled).

OncoPrint™ Reporter: analyses overview

OncoPrint Reporter

https://apps.thermofisher.com/apps/okr/index.html#/analysis

OncoPrint Reporter

Analyses

HomeAnalysesBatch AnalysesSettingsPreferences

Available Credits: 5

To get started, create a new analysis.

Search by name

Search

Create Analysis

Name	File(s)	Cancer Type	Number of Variants	Number of Driver Variants	Report Enabled	Actions
D17-1453	OKB_D17-1453_v2_084d818d-...	Colorectal Cancer	5	0	✓	
D17-1699	OKB_D17-1699_v2_057a7a22-...	Non-Small Cell Lung Cancer	7	4	✓	
D17-1592	OKB_D17-1592_v2_e321c2ea-...	Non-Small Cell Lung Cancer	8	4	✓	
D17-1678	OKB_D17-1678_v2_6041334e-...	Non-Small Cell Lung Cancer	4	2	✓	
D18-1012_CCPv3	OKB_D18-1012_v3_65644f1d-...	Melanoma	8	3	✓	
D18-283	OKB_D18-283_v3_09189dd5-6...	Non-Small Cell Lung Cancer	6	3	✓	
D18-1067	OKB_D18-1067_v2_82da8274-...	Colorectal Cancer	6	2	✓	
D18-1209	OKB_D18-1209_v3_fc4abd6f-c...	Non-Small Cell Lung Cancer	8	1	✓	
D18-1354	OKB_D18-1354_v2_8794d23a-...	Non-Small Cell Lung Cancer	4	1	✓	
D19-132	OKB_D19-132_v2_c0d9b1be-6...	Non-Small Cell Lung Cancer	3	1	✓	

OncoPrint™ Reporter: sample overview

OncoPrint Reporter

https://apps.thermofisher.com/apps/okr/index.html#/filtercontent

OncoPrint Reporter

Analyses

HomeAnalysesBatch AnalysesSettingsPreferencesAvailable Credits: 5

Analysis: D17-1699Cancer Type: Non-Small Cell Lung CancerAssay: OncoPrint Solid Tumour PanelDrivers: 4Files: 1FilterGenerate Report

SummaryDetails

Content Review

	Indicated	Contraindicated
Genomic Alteration		Clinical Trials
☒ EGFR E746_R748del Tier IA	afatinib dacomitinib erlotinib Show more (7)	None 4
☒ EGFR K754E Tier IA	osimertinib	None 0
☒ CTNNB1 S37F Tier None	None	None 0
☒ SMAD4 L529fs Tier None	None	None 0

* Includes biosimilars

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Software Version: v.4.4.0 r.9f9251c | Data Version: 2019.09(005)
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OncoPrint™ Reporter: filter settings

The screenshot displays the OncoPrint Reporter web application. The main interface is divided into a header, a navigation sidebar, a main content area, and a right-hand filter panel.

Header: The top navigation bar includes links for Home, Analyses, Batch Analyses, Settings, and Preferences.

Navigation Sidebar: The left sidebar contains icons for Home, Analyses, Batch Analyses, Settings, and Preferences.

Main Content Area: The central panel shows the analysis details for "D17-1699". It includes a "Summary" tab and a "Details" tab. The "Details" tab is active, showing a "Content Review" section with a table of genomic alterations and relevant therapies.

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer types)
☒ EGFR E746_R748del Tier IA	afatinib dacomitinib erlotinib Show more (7)	None
☒ EGFR K754E Tier IA	osimertinib	None
☒ CTNNB1 S37F Tier None	None	None
☒ SMAD4 L529fs Tier None	None	None

* Includes biosimilars

Right-Hand Filter Panel: The "Filter Content" panel allows users to refine their search. It includes sections for:

- Filter Preset:** A dropdown menu set to "Filter trials NL".
- Data Sources:** A row of checkboxes for FDA, NCCN, EMA, ESMO, and Clinical Trials.
- Marker Types:** A row of checkboxes for Therapeutic, Prognostic, and Diagnostic.
- Clinical Trial Locations:** A dropdown menu set to "Netherlands".
- Clinical Trial Phases:** A dropdown menu set to "I, II, III, IV".
- Include therapies for other cancer types for labels and guidelines?** A dropdown menu set to "Yes (Solid OR Hematological)".

At the bottom of the filter panel are buttons for "Save As New Filter Preset", "Cancel", and "Apply".

Footer: The bottom of the page contains copyright information: "© 2015-2019 Thermo Fisher Scientific Inc. All rights reserved. Software Version: v4.4.0 r9f9251c | Data Version: 2019.09.005" and a disclaimer: "DISCLAIMER: The data presented here is a result of the curation of published data sources, but may not be exhaustive."

OncoPrint™ Reporter: report settings

The screenshot shows the OncoPrint Reporter web application interface. The browser address bar displays the URL: <https://apps.thermofisher.com/apps/okr/index.html#/reportTemplate/702>. The application header includes the title "OncoPrint Reporter" and navigation links: Home, Analyses, Batch Analyses, Settings, Preferences, and Available Credits: 5. The main content area is titled "Report Template Builder" and contains a sub-header "Edit a report template to be used in the protocol outlined by your laboratory." Below this, there are three tabs: "Required Details", "Report Sections", and "Header/Footer Fields". The "Report Sections" tab is active, showing two columns: "Available" and "Included". The "Available" column lists sections: Relevant Cancer Type Findings, Variant Details, Biomarker Descriptions, Version Information, Page Break, Custom Text, and Image. The "Included" column lists sections: Custom Text, Report Highlights, Clinically Significant Biomarkers, Other Prevalent Biomarkers, Variant Details, Variant Class Hierarchy, Tier Criteria Met, Relevant Therapy Summary, Page Break, Relevant Therapy Details, and Clinical Trials Summary. Arrows between the columns allow for moving sections. Below the columns, there is a text input field for "Custom Text Name" and a text area for "Custom Text" with a "(show formatting help)" link. The "Custom Text" area contains sample information placeholders. At the bottom right, there are buttons: Return, Reset, Delete, Save As New, and Save Changes.

OncoPrint Reporter

Report Template Builder

Home Analyses Batch Analyses Settings Preferences Available Credits: 5

Edit a report template to be used in the protocol outlined by your laboratory.

Required Details Report Sections Header/Footer Fields

Back Next

Available

- Relevant Cancer Type Findings
- Variant Details
- Biomarker Descriptions
- Version Information
- Page Break
- Custom Text
- Image

Included

- Custom Text
- Report Highlights
- Clinically Significant Biomarkers
- Other Prevalent Biomarkers
- Variant Details
- Variant Class Hierarchy
- Tier Criteria Met
- Relevant Therapy Summary
- Page Break
- Relevant Therapy Details
- Clinical Trials Summary

Ordered list of sections to include in the report.

Custom Text Name

Enter a name to identify the custom text section. The name is not included in the report.

Custom Text * (show formatting help)

```
**Sample Information**  
  
**Optional Sample Info 1:** {{optional Sample Info 1}}  
**Optional Sample Info 2:** {{optional Sample Info 2}}
```

Sample Information

Optional Sample Info 1: {{Optional Sample Info 1}}
Optional Sample Info 2: {{Optional Sample Info 2}}

Return Reset Delete Save As New Save Changes

Example of Oncomine™ Reporter: Case 1

Sample Information

Optional Sample Info 1: Tnr

Optional Sample Info 2: D17-1592

Sample Cancer Type: Non-Small Cell Lung Cancer

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Report Highlights

3 Clinically Significant Biomarkers

11 Therapies Available

3 Clinical Trials

Example of Oncomine™ Reporter: Case 1

Clinically Significant Biomarkers

■ Indicated ■ Contraindicated

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<i>EGFR p.(L861Q) c.2582T>A</i> epidermal growth factor receptor Tier: IA Allele Frequency: 91.46%	afatinib ^{1,2} dacomitinib erlotinib gefitinib ² osimertinib afatinib + cetuximab gefitinib + chemotherapy bevacizumab + erlotinib bevacizumab + gefitinib atezolizumab + bevacizumab + chemotherapy	None	3
<i>EGFR p.(S768I) c.2303G>T</i> epidermal growth factor receptor Tier: IA Allele Frequency: 90.66%	afatinib ¹ dacomitinib erlotinib gefitinib ² osimertinib afatinib + cetuximab gefitinib + chemotherapy bevacizumab + erlotinib bevacizumab + gefitinib atezolizumab + bevacizumab + chemotherapy	None	2
<i>PIK3CA p.(H1047R) c.3140A>G</i> phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha Tier: IIC Allele Frequency: 30.62%	None	alpelisib + fulvestrant ¹	0

Example of OncoPrint™ Reporter: Case 1

Variant Details

DNA Sequence Variants

Gene	Amino Acid Change	Coding	Variant ID	Locus	Allele Frequency	Transcript	Variant Effect
PIK3CA	p.(H1047R)	c.3140A>G	COSM775	chr3:178952085	30.62%	NM_006218.2	missense
EGFR	p.(S768I)	c.2303G>T	COSM6241	chr7:55249005	90.66%	NM_005228.3	missense
EGFR	p.(L861Q)	c.2582T>A	COSM6213	chr7:55259524	91.46%	NM_005228.3	missense
TP53	p.(G334A)	c.1001G>C	.	chr17:7574026	88.82%	NM_000546.5	missense
FGFR3	p.(=)	c.1959G>A	.	chr4:1807894	100.00%	NM_001163213.1	synonymous
MET	p.(=)	c.534C>T	.	chr7:116339672	66.16%	NM_001127500.1	synonymous
MET	p.(N375S)	c.1124A>G	COSM710	chr7:116340262	67.28%	NM_001127500.1	missense
TP53	p.(P72R)	c.215C>G	.	chr17:7579472	100.00%	NM_000546.5	missense

Example of Oncomine™ Reporter: Case 1

Tier Criteria Met

Genomic Alteration	Tier Classification for Non-Small Cell Lung Cancer
<i>EGFR p.(L861Q) c.2582T>A</i> Tier: IA	IA: Biomarker predicts response or resistance to FDA or EMA approved therapies in this cancer type IA: Biomarker is included in NCCN or ESMO guidelines that predict response or resistance to therapies in this cancer type IIC: Biomarker is an inclusion criteria for clinical trials
<i>EGFR p.(S768I) c.2303G>T</i> Tier: IA	IA: Biomarker predicts response or resistance to FDA or EMA approved therapies in this cancer type IA: Biomarker is included in NCCN or ESMO guidelines that predict response or resistance to therapies in this cancer type IIC: Biomarker is an inclusion criteria for clinical trials
<i>PIK3CA p.(H1047R) c.3140A>G</i> Tier: IIC	IIC: Biomarker predicts response or resistance to FDA or EMA approved therapies in other cancer types

Reference: Li et al. *Standards and Guidelines for the Interpretation and Reporting of Sequence Variants in Cancer: A Joint Consensus Recommendation of the Association for Molecular Pathology, American Society of Clinical Oncology, and College of American Pathologists.* J Mol Diagn. 2017 Jan;19(1):4-23.

Example of Oncomine™ Reporter: Case 1

Clinical Trials Summary

EGFR p.(L861Q) c.2582T>A

NCT ID	Title	Phase
No NCT ID	A Randomized Phase III Study Of Erlotinib Compared To Intercalated Erlotinib With Cisplatinum Pemetrexed As First-Line Therapy For Advanced EGFR Mutated Non-Small-Cell Lung Cancer. The NVALT-17 Study	III
NCT03784599	Trastuzumab-emtansine and Osimertinib Combination Treatment to Target HER2 Bypass Track Resistance in EGFR Mutation Positive NSCLC	II
NCT03114319	An Open-label, Multi-center, Phase I, Dose Finding Study of Oral TNO155 in Adult Patients With Advanced Solid Tumors	I

EGFR p.(S768I) c.2303G>T

NCT ID	Title	Phase
NCT03784599	Trastuzumab-emtansine and Osimertinib Combination Treatment to Target HER2 Bypass Track Resistance in EGFR Mutation Positive NSCLC	II
NCT03114319	An Open-label, Multi-center, Phase I, Dose Finding Study of Oral TNO155 in Adult Patients With Advanced Solid Tumors	I

Example of Oncomine™ Reporter: Case 2

Sample Information

Optional Sample Info 1: Tnr

Optional Sample Info 2: D18-1067

Sample Cancer Type: Colorectal Cancer

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Report Highlights

2 Clinically Significant Biomarkers

1 Therapies Available

5 Clinical Trials

Clinically Significant Biomarkers

■ Indicated ■ Contraindicated

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
<i>PIK3CA p.(E545K) c.1633G>A</i> phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha Tier: IIC Allele Frequency: 29.16%	None	■ alpelisib + fulvestrant ¹	0
<i>KRAS p.(G12S) c.34G>A</i> KRAS proto-oncogene, GTPase Tier: IA Allele Frequency: 56.66%	■ cetuximab ^{1,2} ■ panitumumab ¹ ■ cetuximab + chemotherapy ² ■ panitumumab + chemotherapy ²	None	5

Sources included in relevant therapies: FDA¹, NCCN, EMA², ESMO

Example of OncoPrint™ Reporter: Case 2

Variant Details

DNA Sequence Variants

Gene	Amino Acid Change	Coding	Variant ID	Locus	Allele Frequency	Transcript	Variant Effect
PIK3CA	p.(E545K)	c.1633G>A	COSM125370	chr3:178936091	29.16%	NM_006218.2	missense
KRAS	p.(G12S)	c.34G>A	COSM517	chr12:25398285	56.66%	NM_033360.3	missense
FGFR3	p.(F386L)	c.1156T>C	COSM724	chr4:1806131	57.87%	NM_001163213.1	missense
FGFR3	p.(=)	c.1959G>A	.	chr4:1807894	100.00%	NM_001163213.1	synonymous
EGFR	p.(=)	c.2361G>A	.	chr7:55249063	100.00%	NM_005228.3	synonymous
MET	p.(T1010I)	c.3029C>T	COSM707	chr7:116411990	38.50%	NM_001127500.1	missense

Tier Criteria Met

Genomic Alteration	Tier Classification for Colorectal Cancer
<i>PIK3CA</i> p.(E545K) c.1633G>A Tier: IIC	IIC: Biomarker predicts response or resistance to FDA or EMA approved therapies in other cancer types
<i>KRAS</i> p.(G12S) c.34G>A Tier: IA	IA: Biomarker predicts response or resistance to FDA or EMA approved therapies in this cancer type IA: Biomarker is included in NCCN or ESMO guidelines that predict response or resistance to therapies in this cancer type IIC: Biomarker is included in NCCN or ESMO guidelines that predict response or resistance to therapies in other cancer types IIC: Biomarker is an inclusion criteria for clinical trials

Reference: Li et al. Standards and Guidelines for the Interpretation and Reporting of Sequence Variants in Cancer: A Joint Consensus Recommendation of the Association for Molecular Pathology, American Society of Clinical Oncology, and College of American Pathologists. J Mol Diagn. 2017 Jan;19(1):4-23.

Example of Oncomine™ Reporter: Case 2

Clinical Trials Summary

KRAS p.(G12S) c.34G>A

NCT ID	Title	Phase
NCT02162563	Treatment Strategies in Colorectal Cancer Patients With Initially Unresectable Liver-only Metastases CAIRO5 a Randomized Phase III Study of the Dutch Colorectal Cancer Group (DCCG)	III
NCT02703571	A Phase I/II Study of Safety and Efficacy of Ribociclib (LEE011) in Combination With Trametinib (TMT212) in Patients With Metastatic or Advanced Solid Tumors	I/II
NCT02754141	A Phase I/IIa Study of BMS-986179 Administered Alone and in Combination With Nivolumab (BMS-936558) in Subjects With Advanced Solid Tumors	I/II
NCT03082209	An Open-Label, Phase I, First-In-Human Study of Safety and Tolerability of TRAIL Receptor Agonist ABBV-621 in Subjects With Previously Treated Solid Tumors and Hematologic Malignancies	I
NCT02607813	A Phase I Dose Finding Study of Oral LXH254 in Adult Patients With Advanced Solid Tumors Harboring MAPK Pathway Alterations	I

Conclusions

- Overall impression and benefits
 - Easy to use and navigate through software
 - Analysis is very quick
 - Extensive information on therapeutic options and available trials
 - Possibilities to adapt report to include all the information you need about specific variants

Future directions

- Integration of software in routine diagnostics
 - Some adaptations to current workflow
 - Automated generation of Oncomine Reporter cases from NGS data, instead of manual upload
- Expectations from clinicians
 - Content of report
 - Ease-of-use for clinic
 - Length of report

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