Digitalization along the value chain

Investor Relations Event

17 November 2021
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Agenda

Welcome
  • Karl Mahler, Head of Investor Relations

Digitalization along the value chain
  • Alan Hippe; Chief Financial and IT Officer Roche

Digitalization to improve disease understanding, identify new drug targets and leads
  • Mark McCarthy, Executive Director Human Genetics, gRED

Digitalization to enable early R&D and clinical development
  • Christian Gossens, Digital Biomarkers, Global Area Head, pRED

Real world evidence to improve clinical R&D and patient care
  • Jacqueline Law, Vice president, Head of Corporate Strategy, Flatiron Health

Digital platforms accelerating development, manufacturing and commercialization
  • Steve Guise; Global Head, Pharma Informatics

Roche Information Solutions (RIS): Bringing insights into action for better healthcare
  • Moritz Hartmann, Global Head of Roche Information Solutions, Roche Diagnostics

Q&A
Digitalization along the value chain

**Alan Hippe**  Chief Financial and IT Officer Roche
Industry trends: Our environment is changing at high pace

Roche: Entering new frontiers by providing a digital infrastructure to match changing business needs

A look into the future
Industry disruptions – trends impacting our core business dynamics

Care pathway and delivery

5 Trends:
1. Companies go beyond the pill – try direct to patient approaches
2. Increasing consumerized healthcare (delivery plus digital solution)
3. Patient outcomes easier to measure & manage patient data collected and acted in real time
4. Non-healthcare players entering market creating ecosystems around patients
5. Patient managing their own health – digital services empowered to take decisions

<table>
<thead>
<tr>
<th>Pharma &amp; medical products (e.g., drugs &amp; diagnostic tools)</th>
<th>Technology, data, analytics (e.g., wearables)</th>
<th>Life style/ wellness (e.g., early diagnosis)</th>
<th>Channel (e.g., digital pharmacy)</th>
<th>Care delivery (e.g., &quot;brick and mortar&quot; hospitals &amp; clinics)</th>
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<tbody>
<tr>
<td>Prevention</td>
<td>Diagnosis</td>
<td>Treatment</td>
<td>Channel</td>
<td>Care delivery</td>
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Source: Company financial reports, analyst reports, McKinsey Centre on US Health System Reform, EvaluatePharma, Medicare Payment Advisory Commission, press reports, external expert interviews
Digital maturity in Pharma relatively low compared to other industries

Some improvement over the recent past

Source: BCG, *Global Digital Acceleration Index study 2021. N>2,200 companies, thereof approx. 60 Pharma with >5k employees in 2020 and approx. 50 in 2021; Note: For reasons of readability the sectors Industrial goods, media and entertainment, automotive and consumer have been removed
Digital Health: Capital flows reflect long term growth trends and have spiked through the pandemic

Source: Rock Health Database (2020 Market Insights Report: Chasing a new equilibrium), BCG Analysis
… there are also many well funded digital health players focused on serving the BioPharma industry

<table>
<thead>
<tr>
<th>Value Chain</th>
<th>Discovery</th>
<th>Development</th>
<th>Operations</th>
<th>Go-to-market</th>
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<tbody>
<tr>
<td>Discover target areas and products</td>
<td>• Early biology and product generation</td>
<td>• Clinical trial design and execution</td>
<td>• Product manufacturing</td>
<td>• Pricing and access management</td>
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<td>• Product optimization</td>
<td>• Product and process development</td>
<td>• Distribution/supply chain</td>
<td>• Commercial and marketing</td>
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<td>• Pre-clinical safety assessment</td>
<td>• Regulatory submission</td>
<td>• Quality and compliance</td>
<td>• Medical affairs</td>
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Enabling infrastructure

Source: BCG Analysis
Today’s magnitude of digital across Roche

More than CHF 3bn annual spend in digital across the company

**CHF 3bn+**
annual spend in digital

**300+**
key initiatives ongoing

**50+**
partnerships across data, analytics and digital supporting our continued focus on PHC over the last 3 years

**30+**
solutions on market

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**Recent digital & PHC deals and partnerships**

1. **Foundation Medicine**
   - (molecular information)

2. **Fred Hutch**
   - (digital remote monitoring system)

3. **Flatiron**
   - (electronic health records)

4. **The Alan Turing Institute**
   - (data & analytics to advance PHC)

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1 Non-exhaustive and illustrative overview of deals and partnerships signed over recent years; PHC=personalized healthcare
Digitalization along the value chain

27 Diverse use cases presented today show the depth & breadth of digitalization

1. ASPIRE (creating a digital backbone)
2. myBuy (a new global procurement tool)
Industry trends: Our environment is changing at high pace

Roche: Entering new frontiers by providing a digital infrastructure to match changing business needs

A look into the future
Vision: From data to insights
Empowering domains to manage their own data, while promoting sharing, discovery of data & insights across the enterprise

Converge within individual domains
Federated Roche-wide data & insights ecosystem
Distributed across enterprise

Illustrative
Example: Data to enable integrated use cases

Cross-functional integrated data
Consume data products to support programs that require integrating data across domains

Data products
Expose commonly used data as data products

Functional data environment
Function-specific data & data repositories
Finance: A new data infrastructure

*Enabling the business to meet their analytic and insight needs*

From a fragmented infrastructure...

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<th>Solution / application</th>
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<td>APIs</td>
<td>APIs</td>
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<td>Data backbone</td>
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<tr>
<td>Infra &amp; security</td>
<td>Infra &amp; security</td>
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...to a seamless data infrastructure

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<th>Solution / application</th>
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<th>Solution / application</th>
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<tbody>
<tr>
<td>Common APIs &amp; data marketplace</td>
<td>Foundational data backbone</td>
<td>Foundational infra &amp; security</td>
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API=available application programming interface
Example: Creating a digital backbone in Finance

**Business insights**
- Intuitive user experience consistent across devices
- Support of new business models
- Support mergers & acquisitions

**Speed & flexibility**
- Immediate financial analysis
- Advanced and predictive analytics
- Planning and actuals on the same platform in the same structure

**Productivity**
- End-to-end process integration and automation
- Single source of truth
- Faster closing
- Minimum to no reconciliations

**Risk & compliance**
- Continuous accounting and controls monitoring
- Comprehensive insights into risks
- Integration of compliance into operational processes

**Operations**
- Simplified integrated solutions (less satellite systems)
- Simplified data model and structure
- Consolidated instances and infrastructure

**Value generation for Roche**
## Summary digital in Finance: Creating a digital backbone with ASPIRE

<table>
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<tr>
<th>1</th>
<th>Amongst SAP’s largest S/4HANA projects worldwide</th>
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<tr>
<td>~350</td>
<td>Program team colleagues across the globe</td>
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<td>1</td>
<td>Process house across Roche</td>
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<td>~200</td>
<td>Deployment planned to legal entities</td>
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<td>~700</td>
<td>~100,000 End users (end state)</td>
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<td>~700 level 4 processes in scope</td>
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Co-innovation with SAP & industry consortium

Clinical supply industry solution (CTSM)

**Intelligent clinical supply management (ICSM)**

Building a clinical industry standard solution to supply clinical trials in collaboration with industry consortium:

- Maximize the usage of the SAP Standard capabilities using new SAP S/4HANA technology to support the standardization and the implementation of simplified business processes
- Ensure that clinical supply innovative processes and solutions are implemented by collaborating in the development of the future Clinical supply industry solution (CTSM) with SAP

**Co-innovation as an industry consortium**

1. New product naming
Value creation through digitalization
myBuy in Finance

New global purchasing platform driving easier, faster & more customer focused buying

New technology
myBuy replaces multiple tools

Suppliers
New portal to foster eCollaboration

Financial approvals
Simplified financial approvals with dedicated approval thresholds

User experience
Enhanced content, new ways to buy and more self-service opportunities

Policies
Update and enable Roche’s procurement policies and Genentech purchasing guidelines

Support
Further digitize the processes to deliver RSS services

What have we achieved so far?

- myBuy platform live since July 2020 with strong user adoption
- 1’700 content items developed for Basel and GNE, enabling high levels of automation and self-service (e.g. targeting >80% content-based transactions for Basel)
- ~40% reduction of downstream suppliers for Basel
Increasing number of applications are adopting cloud-based platforms

Increasing external collaborations require data and insights that can easily be shared (in a neutral environment), need cloud-based capabilities to support “neutral zones”

Support for multiple data modalities require more flexible, scalable infrastructure that can adapt quickly to emerging needs

Decentralized model for data & analytics require different analytics capabilities
Industry trends: Our environment is changing at high pace

Roche: Entering new frontiers - providing a digital infrastructure to match changing business needs

A look into the future
Digitalization along the value chain

What digitalization delivers to Roche, healthcare systems and patients

- Digital Infrastructure & Group functions
  - Early R&D
  - Clinical Development
  - Regulatory & Reimbursement
  - Manufacturing & Distribution
  - Commercialisation
  - Diagnosis
  - Treatment Support Physicians & Patients

- New insights in biology
- New insights in human disease
- New drug targets & drugs
- Speed to market & improved health economic assessment
- Highly individualized drugs
- Improved access
- Improved diagnosis
- Improved treatment options & support
- New insights in human disease

EFFICIENCY GAINS all along the way

More patient benefits at reduced cost to society
Digitalization to improve disease understanding, identify new drug targets and leads

Mark McCarthy | Executive Director Human Genetics, gRED
Digitalization impacting our entire value chain

Human genetics help uncover potential new drug targets
Genetics and its impact on checkpoint inhibition
Single cell RNA transcription profiling
Antibiotics discovery applying advanced virtual drug screening
Levers to transform drug discovery

Multiplicative levers to transform understanding of disease biology and our capacity to modify causal pathways

Delivering more medicines for less cost to society

Focus on a diversity of digital data
Enable understanding of patient and disease heterogeneity and its relevance to clinical outcome at unprecedented resolution
A diversity of data

*Human genetics is in vivo functional biology in the species we most care about*

Targets with human genetic support have ~2x the PTS of targets that do not

Nelson, Nat Gen, 2015; King, PLoS Genetics, 2019

Wang et al, Nature, 2021

Natural experiments of genetic perturbation

Clinical experiments of therapeutic perturbation

Table 1. The relative value of genetic support for the probability that a target-indication pair progresses along the drug development pipeline, based on historical drug trial information.

<table>
<thead>
<tr>
<th>Progression (genetic support/Variant):Progression (no genetic support)</th>
<th>GWASdb and OMIM</th>
<th>GWASdb</th>
<th>OMIM</th>
</tr>
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<tbody>
<tr>
<td>Phase I to phase II: 1.2 (1.1-1.3)</td>
<td>1.2 (1.1-1.3)</td>
<td>1.2 (1.1-1.3)</td>
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<tr>
<td>Phase II to phase III: 1.5 (1.3-1.7)</td>
<td>1.4 (1.2-1.7)</td>
<td>1.6 (1.3-1.9)</td>
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<tr>
<td>Phase III to approval: 1.1 (1.0-1.2)</td>
<td>1.0 (0.8-1.2)</td>
<td>1.1 (0.9-1.3)</td>
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</tr>
<tr>
<td>Phase I to phase III: 1.8 (1.5-2.1)</td>
<td>1.8 (1.4-2.1)</td>
<td>1.9 (1.5-2.3)</td>
<td></td>
</tr>
<tr>
<td>Phase I to approval: 2.0 (1.6-2.4)</td>
<td>1.8 (1.3-2.3)</td>
<td>2.2 (1.6-2.8)</td>
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</tr>
</tbody>
</table>

Values give the ratio of the probability of a target-indication pair progressing given genetic support to the probability of progressing without genetic support. 95% confidence intervals are given in parentheses.
The search for human diversity just started

- Diversity
- Power for discovery
- Greater clinical relevance
- Integration with health care

Mutations in every one of the 3 billion bases in the human genome (provided compatible with life) is present in dozens of people on the globe
Human genetics help uncover potential new drug targets

**ANGPTL7 loss of function mutation protects against glaucoma**

Using genotyping data from the UK Biobank (n=337,151) and FinnGen (n=176,899) a search for protein-altering variants conferring lower intraocular pressure and protecting against glaucoma was performed.

- «Rare protein-altering variant association analysis» identified 5 variants of the **ANGPTL7** gene (including missense and truncation mutations) pointing towards a protective mechanism caused by loss of ANGPTL7 interaction and/or function.

- These results strongly support the inhibition or down-regulation of ANGPTL7 as a therapeutic strategy for glaucoma.

**PheWAS in UK Biobank**

- **Glucoma type**
  - ALL: 8,537 cases, 170,362 controls
  - Angiopoietin-related protein 7 (ANGPTL7) = PheWAS in UK Biobank

- **Glucoma analysis in individuals without IOP measurements (not in Analysis 1)**
  - 4,239 cases, 250,660 controls
  - p.Gln179His (rs28991009) = 3 variants

- **Analysis 1:** Rare protein-altering variants genome-wide association scan
  - Intracocular pressure analysis (n = 32,250 individuals)
  - 41,590 genotyped variants, 14,366 genes
  - **P = 10^-8**
    - ANGPTL7 p.Gln179His (rs28991009)
    - MAF: 0.8%
    - Combined Left and Right eye: **P = 3.93x10^-10**
  - **P = 2.5x10^-8**
    - ANGPTL7 (burden test, dispersion test) ALL: without p.Gln179His
      - Combined Left and Right eye: **P = 1.85x10^-14, 1.43x10^-16, 5.81x10^-16**
      - **P = 1.44x10^-16, 2.82x10^-16, 2.39x10^-14**
      - **P = 1.20x10^-13**

- **Analysis 2:** Glaucoma analysis
  - 8,537 cases, 170,362 controls
  - ANGPTL7 p.Arg220Cys (rs147660927) = 1-1253817-C:T
  - MAF: 4.3% in Finland, 0.1% in UK

- **Analysis 3:** Glaucoma analysis in individuals without IOP measurements (not in Analysis 1)
  - 4,239 cases, 250,660 controls
  - p.Gln179His (rs28991009) = 1-1253817-C:T
  - **P = 6.2x10^-8, OR = 0.97**
    - ANGPTL7 (burden test, dispersion test) ALL: without p. Gln179His
      - **P = 8.3129, 7.7x10^-16, 7.72, 0.72**

- **Test hypothesis:** **ANGPTL7 in Glaucoma**

Tanigawa Y. et al.; Plos Genetics, 2020 May 5; ANGPTL7 = Angiopoietin-related protein 7
A meta-analysis of Tecentriq trials shows that Tecentriq-induced thyroid dysfunction is associated with longer survival.

We construct a polygenic risk score (PRS) for lifetime risk of hypothyroidism using a GWAS from the UK Biobank (25,000 thyroiditis cases) and apply this PRS to genetic data collected from 2,616 patients of European ancestry from these trials.

Patients with high PRS are at increased risk of Tecentriq-induced thyroid dysfunction and potentially greater OS in TNBC.

Khan Z. et al.; Nature Communication, 2021 June 7; HR=hazard ratio; OS=overall survival; irAE=immune related adverse event; GWAS=genome wide association study; PRS=prognostic risk score; TNBC=triple negative breast cancer.
Single cell RNA transcription profiling

Mapping the biological impact of COVID-19 infection in human cell types

Isolation of single infected lung cells and gene expression profiling

• Infected and non-infected cells from 17 individuals who succumbed to COVID19 were isolated from different tissues
• Single-cell and single-nucleus RNA sequencing in combination with a computational framework allowed for automated cell type annotation to facilitate comparison with other healthy and diseased tissue atlases
• Overall, the COVID-19 cell atlas created serves as a foundational dataset to better understand the biological impact of SARS-CoV-2 infection across the human body and empowers the identification of new therapeutic intervention strategies

Advances in computing and math make the bigness of biology, chemistry and medicine a new advantage.

Potential breakthrough goal: be predictive and explanatory (mechanistic) in biology, chemistry and medicine.
Antibiotics discovery

Machine learning and artificial intelligence improve virtual drug screening

Virtual drug screening

Applying AI and ML to virtual drug screening

- Up to 2m compounds are screened in a single HTS, but the space of available compounds is estimated to be $>> 10^{23}$
- A major challenge of virtual drug screening is that only molecules similar to the training set get identified

- Applying artificial intelligence (AI) and machine learning (ML) might overcome traditional limitations of virtual drug screening approaches and complement physics-based methods (e.g., docking)
- Input data is only the molecular structure and the chemistry is learned from unlabeled compounds
- HTS data are only used as training sets for well-defined tasks

We've been working on virtual screening for decades, with a level of success that can be characterized as quite variable but (to be honest) often underwhelming.

Derek Lowe, Science (2020)
Antibiotics discovery

Identifying new lead structures with antibacterial properties

An algorithm applying AI and ML and trained on 122m unlabeled public compounds successfully clusters known antibiotics based on their chemical properties.

The algorithm was able to identify active molecules highly different from the training set allowing the identification of new lead structures.

~500 small molecules predicted to be active have been ordered. First experimental results expected in Q1 2022. Experimentally verified active molecules could provide new hits for medicinal chemistry hit-to-lead optimization.

Data provided by Tommaso Biancalani; Gabriele Scalia (AI/ML); Steven Rutherford (ID); Nick Skelton (SMDD); Ziqing Lu; Ignacio Aligas; Leo Gendelev; Jeff Blaney
Future of digital data in early research

Human biology, high resolution and massive scale methods

- Novel disease pathways
- Oncogene coding variants classes
- Cell therapy states
- Gene therapy
- Cell biology phenotypic screens
- Large scale drug/target combinations
- Systematic toxicity prediction

- Acceleration of biological insights
- Systematic discovery of targets and biomarkers
- More efficient target prioritization and development (efficacy, safety, tractability)
- Delivery of personalized medicine
Digitalization to enable early R&D and clinical development

Christian Gossens | Digital Biomarkers, Global Area Head, pRED
Digitalization impacting our entire value chain

- Early R&D
- Clinical Development
- Regulatory & Reimbursement
- Manufacturing & Distribution
- Commercialization
- Diagnosis
- Treatment Support Physicians & Patients

1. Quantum computing task force
2. Fully automated in vivo research
3. Improved diagnosis in ophthalmology (nAMD) using AI
4. Digital biomarker data collection during the pandemic
5. Digital biomarker development in PD
6. Floodlight in MS market appearance
Transform the scientific and research experience

- Increase the power of predictive algorithms for drug efficacy and safety
- Make augmented drug design the norm
- Enable self-service data analysis

Better understand patients and the science behind the diseases

- Gain deeper insights into patient needs and their communities
- Improve patient engagement and experience with personalised health services
- Better understand biological systems, pioneering the use of in silico models

Optimise the pRED operational engine

- Deliver easy access to data and information, including external data
- Enable seamless, end-to-end digital workflows
- Leverage automation and AI to enhance scientific and operational decision making

Transform the research experience for scientists through leading digital capabilities to achieve breakthroughs in medicine, deliver greater value for patients and sustainably increase pRED’s productivity
One-D: Investing to sustainably increase pRED’s productivity

Driving fundamental shift in how science is done with a significant move towards in-silico modeling and data-based decision making

Increase pRED’s productivity by ~20% phasing now to 2025

Generating insights beyond conventional knowledge with a longer-term impact on R&D, uniting our people’s expertise with AI and open access to data

Examples: Reduction of animal studies, advances in institutional learning, and improved talent attraction and retention

Productivity \( \frac{WIP \times p(TS) \times Value}{Cycle\ Time \times Costs} \)
Roche pRED Quantum Computing (QC) Taskforce

Evaluate QC to simulate drug action on proteins and to accelerate machine learning

- Established 2.5 years ago
- Explore if quantum advantage* exists for Roche relevant use cases
- Understand QC hardware approaches and software (algorithms) and contribute to fundamental research
- Play an active role in the QC ecosystem
- Shape the QC roadmap for Roche

Roche use cases

**Chemistry simulation**


**Protein folding**


**Image classification**


* quantum computers can have a significant advantage over classical computers by reducing compute time for specific algorithms due to exponential speed up.
pRED in vivo research moved to an award winning facility

**Fully automated cage preparation**

*2020 Facility of the Year Award Winners*

- Q. F. Hoffmann-La Roche Ltd.
  - Equipment Innovation

- Locatone Doss, Switzerland
  - Project: 2020. Setting the New Standards for in vivo Building

• Reducing manual labour and improving occupational hygiene for researchers

**Digitally controlled in vivo laboratories**

• Enabling complete, precise control of the lab environment in which experiments are conducted

Source: https://ispe.org/facility-year-awards/winners/2020/equipment-innovation
Image analysis and machine learning in ophthalmology
Non-invasive, automatic identification of lesion type in nAMD using deep learning

- Neovascular AMD (nAMD) manifests in different types, which are important biomarkers for tailored treatment
- The assessment uses an invasive, slow, and costly procedure
- We used non-invasive 3-D tomography scans (SD-OCT) from eyes with one of two lesion types (occult or classic type)
- We applied deep learning for pixel-level detection of pathologies and retinal landmarks
- The two phenotypes could be discriminated with high accuracy

Machine learning can automatically and reliably detect CNV type using SD-OCT at an individual patient level

1) Maunz et al. 2021; CNV=Choroidal Neovascularization; SD-OCT=Spectral domain optical coherence tomography; AMD=age-related macular degeneration
Digital endpoints to drive scientific progress
Delivering new patient insights and building holistic solutions for patients

- Clinical trials utilizing mobiles, wearables and gaming devices
- More sensitive, precise and objective data collection and monitoring of disease progression
- Continuous and longitudinal measurement captures episodic and rare events
- Reduced assessment burden and greater real-world relevance benefiting physicians and patients

### Broad development program in neuroscience

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<tr>
<th>Disease Area</th>
<th>Cognition</th>
<th>Hand Motor Function</th>
<th>Gait &amp; Balance</th>
<th>Vocalization</th>
<th>Activity &amp; sociability</th>
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<td>Parkinson</td>
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<td>Huntington</td>
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<td>SMA</td>
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<td>Multiple Sclerosis</td>
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<td>Alzheimer</td>
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<td>Autism</td>
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<td>Schizophrenia</td>
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### Continuous product improvement
Digital biomarker adherence during the pandemic largely unaffected

COVID-19 impacted clinical trial conduct in Q1/2 2020

- COVID-19 challenged clinical trials with 23 out of 25 pharma companies reporting moderate-high operational impact
- Patients did not travel to sites and sites were shut down for clinical research restricting monitoring

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**COVID-19 impacted people’s daily routines and reduced life space of study participants**

- **High**
- **Low**

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**Digital biomarker study participant test adherence unaffected**

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Thanks to digital biomarkers, patients remained connected with Roche researchers; Data collection continued unimpacted by lock downs and allows further in-depth analysis

Digital biomarkers support clinical drug development

Remote and objective assessments: e.g. Parkinson’s disease

- Daily at home assessment for 6 months
- Ph Ib digital biomarker results

The digital biomarker test suite on the smart phone enables daily quantification of fluctuating symptoms in Parkinson’s disease.

- Preliminary data show clinical validity, strong patient adherence and high test-retest reliability.
- Digital endpoints provide already today decision-making support for drug development.
- Potential future use in patient & treatment monitoring, identifying subclinical signs in prodromal patients, or as primary outcomes measures.

Lipsmeier et al., 2018
Parkinson’s disease: Prasinezumab with signals of efficacy in Ph II
Ph IIb started to collect additional data on potential endpoints

Ph II (PASADENA part 1) results at 52 weeks...

• Ph II (PASADENA) study did not meet its primary endpoint (MDS UPDRS total score)
• Prasinezumab was well tolerated showing efficacy signals in slowing of clinical decline of motor symptoms (MDS UPDRS part III, digital motor outcome measures) warranting further follow up
• Ph IIb (PADOVA) started in 2021 in patients with early PD that are on symptomics including L-DOPA

...and follow-up at 104 weeks
Towards regulatory acceptance of digital drug endpoints: Collaboration across the scientific community & industry is key

Building consensus through public-private partnerships, including universities, SMEs, pharma companies, patient organisations and regulators

Creating alignment across the biopharmaceutical sector through integrated cross-industry collaboration

Working with regulatory agencies to shape future guidance and enable drug approval based on digital endpoints

Engaging scientists from industry and academia and FDA to shape aligned positions and enable collaborative projects

Engaging health technology assessment bodies to enable reimbursement decisions based on data derived from digital health technology

Safer and faster drug approvals

BioPharma industry

Patients

Public-private partnership

Scientific community

Healthcare providers

Regulatory agencies

Health technology assessment bodies

Technology providers

(1) Taylor et al., 2020, (2) Stephenson et al., 2020
Multiple sclerosis: Floodlight launched in US and EU
Building ecosystems to serve patients, society and scientific progress

Value creation for patients

- MS progression, often undetected by current clinical scales
- Provides an objective assessment of disease status; empowers patients in shared decision making, enhancing earlier access to care
- Closely co-created with patient communities; studies show high retention rates

"The tasks were all straightforward, and some almost fun."  
Our 1st patient

Concept is spot on.  
US Neurologist

Value creation for science

- Rigor of measurements & robust development define new standards
- Generate disease insights and support future drug development
- Collaborations create consensus on new digital measurements

"I'm 100% behind the initiative and am very enthusiastic about it. It's cool that this was clearly under development before the pandemic and it fits well with my challenges: 90% of patients are virtual and there are lots of time constraints between clinical visits."  
Dr. Shin

Value creation for society

- Earlier intervention has the potential to improve health outcomes and reduce long term health care costs
- Floodlight MS is launched in close collaboration with healthcare providers, enabling RWD opportunities that improve health care utilization

Pharma vision 2030: Providing more patient benefit at less cost to society

SaMD=software as medical device
Real world evidence to improve clinical R&D and patient care

Jacqueline Law | Vice president, Head of Corporate Strategy, Flatiron Health
Digitalization impacting our entire value chain

1. Kadcyla safety update in HER2+ BC
2. Tecentriq positive reimbursement decision in mNSCLC
3. CGDB to drive scientific hypothesis generation
4. PCG novel data collection platform to improve clinical development
5. EHR-claims data to enhance understanding of cancer patient journey
6. Clinico-scan database for research and developing AI-based algorithms
7. Flatiron Assist™ for streamlined clinical decision support
8. Novel Clinical Research Platform to improve clinical development
Flatiron Health®
Transform the way cancer is treated and researched around the globe by developing disruptive and durable technology and scientific solutions

3M patient records available for research, from community practices and academic centers

>280 community cancer centers use Flatiron’s EHR OncoEMR®

7 academic centers partner on scientific research & quality improvement

800 sites of care with >2,000 doctors

4 countries offices in New York, San Francisco, Tokyo, Berlin and London

2,500 employees including engineers, clinicians, data scientists, epidemiologists, and many other experts

Partnerships with National Cancer Institute, U.S. Food & Drug Administration, National Institute for Health and Care Excellence (UK), and many others

Flatiron Health® is an independent affiliate of the Roche Group.
High-priority investments for Flatiron

Real-World Evidence
Expanding real-world data depth, breadth, and modalities to support R&D, regulatory and access

Clinical Research
Transforming clinical study execution to bridge research and real-world care

Scientific Innovations
Advancing novel methodology and approaches with stakeholders to increase the use and acceptance of RWE

Cancer Care
Empowering precision medicine and value-based care to improve patient outcomes

RWE=real world evidence
Flatiron curates high-quality RWD from structured and unstructured data in EHRs and other sources.

Our data can be traced back to the source EHR to ensure consistency and auditability.

RWD=real world data; EHR=electronic health records; RWE=real world evidence
Biopharma partners have used Flatiron RWD to address evidence gaps and generate actionable insights across product lifecycle

<table>
<thead>
<tr>
<th>1 Discovery/Translational</th>
<th>2 Clinical Development</th>
<th>3 Regulatory Approval</th>
<th>4 Market Access</th>
<th>5 Post-Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>MOA / resistance</td>
<td>Trial design</td>
<td>Characterizing unmet need</td>
<td>Benchmark/ natural history</td>
<td>Real-world effectiveness</td>
</tr>
<tr>
<td>Target identification/prioritization</td>
<td>Patient recruitment</td>
<td>Benchmark/ natural history</td>
<td>Long-term survival extrapolation</td>
<td>Real-world safety</td>
</tr>
<tr>
<td>Biomarker selection</td>
<td>Treatment patterns/standard of care</td>
<td>External control</td>
<td>Indirect treatment comparison</td>
<td>Commercial planning</td>
</tr>
<tr>
<td>Identifying unmet need</td>
<td>Characterizing patient population</td>
<td></td>
<td>Real-world/ cost effectiveness</td>
<td></td>
</tr>
</tbody>
</table>

(Red-world data; MOA=mechanism of action)
Flatiron collaborates with many to advance RWE for regulatory and HTA decision-making

<table>
<thead>
<tr>
<th>With Regulators and HTA</th>
<th>Policy &amp; Advocacy</th>
<th>Thought leadership</th>
</tr>
</thead>
<tbody>
<tr>
<td>With FDA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>● 5+ years of partnership</td>
<td>● Friends of Cancer Research (FoCR)</td>
<td>● Active participants in key RWE stakeholder initiatives and alliances including:</td>
</tr>
<tr>
<td>● 7 co-authored publications</td>
<td>● Co-authored 2 publications e.g. real-world endpoints</td>
<td>● Duke Margolis RWE Collaborative</td>
</tr>
<tr>
<td>● 2 FDA workshops</td>
<td></td>
<td>● FoCR pilot projects</td>
</tr>
<tr>
<td>Increased engagement with ex-US regulators</td>
<td>Duke Margolis Center for Health Policy</td>
<td>● Personalized Medicine Coalition</td>
</tr>
<tr>
<td>● EMA, PMDA</td>
<td>● Contributed to 3 RWE frameworks in 2019</td>
<td>● ISPOR Transparency initiative</td>
</tr>
<tr>
<td>With NICE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>● 3-year research collaboration</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

RWE=real world evidence; HTA=health technology assessment; FDA=Food & Drug Administration; EMA=European Medicines Agency; NICE=National Institute for health and Care Excellence; ISPOR=The Professional Society for Health Economics and Outcomes Research
Case Study - KADCYLA: RWE led to label change in EU

**SITUATION**
- Limited safety information in patients with low LVEF
- EMA required sponsor to submit data to support post-approval risk management plan
- Prospective study was not feasible due to low prevalence of patient population

**APPROACH**
- Flatiron used novel abstraction approach to enable a retrospective study of cardiotoxicity risk for low LVEF patients receiving KADCYLA

**IMPACT**
- KADCYLA label updated with safety information from RWE study
- Flatiron RWD let sponsor submit data ~5 years earlier than a prospective study would have allowed

**Updated EU label (SmPC or Summary of Product Characteristics) for KADCYLA**

4.4 Special warnings and precautions for use:

- Left ventricular dysfunction ...

4.8 Undesirable effects

- Left ventricular dysfunction

**Value Drivers**

- Traceability to source data
- Clinical Breadth and Depth
- Recency & longitudinality

**Link**: PASS Study

---

RWE=real world evidence; LVEF=left ventricular ejection fraction; EMA-European Medicines Agency; RWD=real world data
Case Study - TECENTRIQ: RWE reversed NICE decisions on coverage

SITUATION
- NICE initially provided a negative draft assessment on the reimbursement for TECENTRIQ in locally advanced or metastatic NSCLC after chemotherapy
- The assessment was based on Expert Review Group approach to estimate 5-year survival of the comparator

APPROACH
- Flatiron data was used to estimate the long-term survival of the comparator and showed that the NICE 5-year survival estimates were inappropriately low and inconsistent with contemporary experience

IMPACT
- NICE agreed with sponsor’s methodology, contributing to a positive coverage decision for TECENTRIQ

“The committee accepted that overall survival at 5 years is likely to be similar to that predicted for other immunotherapies”
– NICE Appraisal (ID970)

Value Drivers
- Mortality Variable
- Recency
- Scientific Rigor

RWE=real world evidence; NICE=National Institute for health and Care Excellence
Flatiron and FMI have built a comprehensive real-world Clinico-Genomic Database (CGDB) to accelerate precision oncology.

**CGDB**

- **~87,000 patients**

**Clinically meaningful cancer genomic data**

- **Proven portfolio of tests** including solid tumor, liquid biopsy, heme, and PD-L1
- **Comprehensive gene panel** (300+ genes on F1CDx) tested on every sample
- **Genomic alterations**: Substitutions, indels, copy number alterations, fusions
- **Computational genomic signatures**: TMB, MSI, LOH
- **Access to source genomic data** with deeper research-only genomic detail compared to PDF reports

**Disease-specific clinical data**

- **Clinical depth/breadth** that captures the detailed patient journey
- **Clinically meaningful real-world outcomes**, including mortality, progression, and response
- **Disease-specific biomarkers & prognostic factors**
- **3 month recency** allows for contemporaneous analysis
- **Data traceability** back to source information
Prospective Clinico-Genomic (PCG): A novel technology-enabled prospective data collection platform

**STUDY OBJECTIVES**
- To evaluate the feasibility of a scalable and prospective platform
- To evaluate serial ctDNA as a predictor for response to therapy for metastatic lung cancer patients

- **STUDY EXECUTION**
  - Achieved 950 patients in 18 months (during COVID)
  - 0 EDC fields needed

- **DIFFERENTIATORS**
  Reduced operational burden and streamlined workflows at the point of care to maximize patient enrollment

“The PCG Study has the potential to help transform how clinical trials are conducted, ultimately making research more feasible for all sites and increasing the number of trial opportunities for patients.”

- Dr. Lee Schwartzberg, chief medical officer at OneOncology

---

.ctDNA=circulating tumor DNA; NSCLC=non-small cell lung cancer; NGS=next generation sequencing; EDC=electronic data capture

59
Recent high-impact use cases using Flatiron clinical and clinical-genomics data

<table>
<thead>
<tr>
<th>Use Case</th>
<th>Description</th>
<th>Presented at:</th>
</tr>
</thead>
<tbody>
<tr>
<td>External Control</td>
<td>Building external control arms from patient-level electronic health record data to replicate the randomized IMBlaze370 control arm in metastatic colorectal cancer</td>
<td>JCO 2021</td>
</tr>
<tr>
<td>Disease Characterization &amp; Testing Patterns</td>
<td>Concordance of HER2+ status by IHC/ISH and ERBB2 status by NGS in a real-world clinicogenomic database and analysis of outcomes in patients (pts) with metastatic breast cancer (mBC)</td>
<td>ASCO 2021</td>
</tr>
<tr>
<td>Clinical Trial Design</td>
<td>Evaluating eligibility criteria using real-world data and AI</td>
<td>Nature 2021</td>
</tr>
<tr>
<td>Disease Characterization by Biomarker</td>
<td>Natural history of patients (pts) with advanced cholangiocarcinoma (CCA) with FGFR2 gene fusion/rearrangement or wild-type (WT) FGFR2</td>
<td>ASCO 2021</td>
</tr>
<tr>
<td>Race and Ethnic Disparities</td>
<td>Racial disparities in biomarker testing and clinical trial enrollment in non-small cell lung cancer (NSCLC)</td>
<td>ASCO 2021</td>
</tr>
<tr>
<td>Testing Patterns</td>
<td>Real-world biomarker testing rates in metastatic colorectal cancer in the United States</td>
<td>ISPOR 2021</td>
</tr>
<tr>
<td>Real World Effectiveness</td>
<td>Real-world data of Palbociclib in combination with endocrine therapy for the treatment of metastatic breast cancer in men</td>
<td>CPT 2021</td>
</tr>
<tr>
<td>Testing &amp; Treatment Patterns</td>
<td>Real-world next-generation sequencing (NGS) and treatment (Tx) patterns in non-small cell lung cancer (NSCLC) patients (pts) with MET exon 14 skipping mutations (METex14)</td>
<td>ESMO 2021</td>
</tr>
<tr>
<td>Real-World Effectiveness</td>
<td>Real-world study of patients with EGFR mutated locally advanced and metastatic non-small cell lung cancer treated with first-line osimertinib</td>
<td>JTO 2021</td>
</tr>
</tbody>
</table>

(Non-exhaustive)
Flatiron and Komodo Health have developed an EHR-claims database to support a wider range of real-world research questions.

Real-world, longitudinal patient-level clinical data from Electronic Health Records (EHRs) from cancer clinics

Healthcare Map includes longitudinal claims data from multiple payers and clearing houses, as well as from direct payer relationships

- Linked counts with closed claims represent **10-20% of Flatiron research database today**\(^1\) and is expected to grow

EHR-claims data can **enhance our understanding of cancer patients’ journeys** and enable use cases such as:

- Healthcare resource utilization studies
- Treatment persistence / adherence studies
- Patient journeys outside of oncology sites of care
- Studies of adverse effects, comorbidities and concomitant medications

---

\(^1\) Projected counts based on actuals available July 2021
Flatiron clinico-scan data support real-world research questions and AI algorithm development

Clinico-scan data can support both real-world research questions and AI algorithm development such as:

- Supplementing real-world outcomes like response and progression
- Developing machine learning algorithms to automate human read
- Deriving new surrogate endpoints
- Developing radiomics-based prognostic and/or predictive biomarker

- Over 1.2M scans from ~280,000 unique patients\(^1\), from 9 practices, and growing
- Across 21 tumor types
- Modalities include CT, PET/CT and MRI
- Longitudinally linked with clinical data and genomics data

\(^1\) Projected counts based on actuals available Oct 2021; AI=artificial intelligence; CT=computed tomography; PET=positron emission tomography; MRI=magnetic resonance imaging
Flatiron technology solutions enable better patient experience, a healthier practice and smarter research

Flatiron Assist™ supports evidence based care and streamlined clinical decision support:

- Biomarker-based treatment decision
- Biomarker-matched clinical trial options
- Support for biosimilar substitutions
Flatiron is building a novel platform to bridge real-world care and clinical research

Select product discovery spaces

- **Trials Enablement Platform**
  - Significantly accelerate clinical research via EHR embedded software

- **RWE**

- **Patient Accrual**

- **Data Management Platform**
  - (Intentional Data Capture, EHR - EDC)

- **Prospective In-Network Studies**
  - Generate prospective evidence more efficiently to unlock novel insights
Digital platforms accelerating development, manufacturing and commercialization

Steve Guise / Global Head, Pharma Informatics
Digitalization impacting our entire value chain

Digital Infrastructure & Group functions

- Early R&D
- Clinical Development
- Regulatory & Reimbursement
- Manufacturing & Distribution
- Commercialization
- Diagnosis
- Treatment Support Physicians & Patients

- EpiCX (Customer engagement)
- CTO (Clinical Trials Optimization tool)
- PACE (Patient Assistance and Care Experience)
- Manufacturing of cell, gene and RNA therapies
- Pandemic response
Our vision is anchored on a bold aspiration

*Our customer experience is as transformative as our science*

---

**Integrated healthcare play by 2030**

**Ecosystem play by 2026**

**Stakeholder play by 2023**

- Consistently engage **key stakeholders** through digital and new customer facing models, including HCPs, patients, payers, policymakers, investigators etc.
- Industry leading customer experience

---

**Transform the healthcare ecosystem and deliver the next wave of innovations through increasingly integrating Roche offerings** (One Roche ambition)

---

**Value creation for the broader ecosystem**

**Reputation of integrated healthcare player**

---

**Integrate different parts of the business in line with the One Roche ambition** (e.g., PHC, diagnostics) to enable business model transformation and drive efficiencies in the healthcare system

---

**Customers:** Simple, consistent, seamless engagements to provide best care

**Roche:** Advancing our leadership position in driving better patient outcomes

---

HCP=healthcare professionals; PHC=personalized healthcare
EpiCX: Building a modern and interoperable technology and data backbone for digital customer enablement

Product ecosystem

- A unified digital customer engagement interface that guides and orchestrates external interactions with Roche's customers across the world.
- A comprehensive content management tool that facilitates efficient development and sharing of commercial and medical content across the organization.
- Achieve deeper customer understanding through creation of a sophisticated and aligned analytics system that allows customers to be understood in detail.
- Master Data Management solutions enable a centralized infrastructure and standardized processes to manage master data across commercial, medical, and customer touchpoints.

Integrated cycle of customer intelligence

- Primary point of contact through common data
- EpiCX customer & content intelligence
  - 360 View of Customer: Our technological backbone that connects us with a seamless view of our customer interactions
- Analytics: Customer journey, needs/insights (e.g. Personify, One Customer, Next Best Actions)
- Capture of digital source and content
- Customer Engagement
  - Face-to-Face and Digital Systems of Engagement, Remote Channels, Services & Solutions
- Affiliate-driven networks

KPI= key performance indicator; EpiCX= Expic Customer Experience
EpiCX roll-out: Content management system (VVPM) and centralised services (Lab) for digital content production

As of November 2021:
- Launched VVPM in 100+ countries with approx 9400+ users trained
- Active material in the ecosystem for sharing reached >60,000 documents
- Central content services rolled out in 15+ affiliates (all affiliates by Q2 2022) targeting cost efficiencies of approx 15-30% for content production
- Average material reuse ~14% with certain affiliates within Lab services having 78% reuse*

* Based on the numbers received from total Lab projects in France from Jan till Nov 2021
Digitalization is changing the way we run our clinical trials

• Across the industry almost 80% of all clinical trials fail to finish on time

• Selecting investigative sites is an important step to the clinical trial process

• Many clinical teams don’t currently have a data-driven approach to determine site productivity

• This can lead to time wasted in the site feasibility and the selection of sites that won’t meet study milestones

Clinical Trials Optimization Tool (CTO)

• Single source of information to select and monitor sites
• CTO utilises machine learning for predictive ranking
• 26k+ internal study sites, 30+ measures, 300k+ competitor studies, 470k principal investigators, 800m claims, 160k sites

Potential benefits
• 36% time savings from automation
• Reducing non-performing sites
• Uncovers “hidden” sites and principal investigators
Enhancing patient experience through engagement capabilities and unified view of patient information

• Field patient-facing roles have to hunt down information spread between between multiple systems, and having disjointed and inconsistent information

• Patient relationship management tool based on Salesforce technology enabling to deliver and optimize patient assistance services ensuring seamless, consistent, and meaningful patient engagement

• Used by Evrysdi, Hemlibra, Esbriet and Enspryng patient facing teams
Manufacturing individualized cell and gene & (incl. RNA) therapies

**Existing drug modalities**

**One Batch – Many Patients**
*Pure “Make to Stock”*
e.g. small molecules; antibodies

**Highly individualized therapies**

**One Batch – One Patient**
*“Make to Order”*
e.g. CARTs, RNA vaccines in oncology (iNEST)

**Individualized therapies**

**One Batch – Several Patients**
*“Make to Stock” with make to order kit*
e.g. off-the-shelf CARTs, gene therapies, RNA therapies

Supply chain driven by new KPIs
Wait time, TAT, Zero Error SC.

Unique requirements
Order Management, Col/CoC, Protected health information, Make to Order scheduling, performance management & workflow management.

New orchestration and exception management

Ensuring the right patient is treated with the right product at the right time with zero error in the value chain

Col/CoC=chain of custody/chain of identity; NGS=next generation sequencing; LSC&D=late stage customisation & distribution; CARTs=Chimeric antigen receptor T-cells; iNEST=Individualized NeoAntigen Specific Immunotherapy
New digital capabilities enabling individualized therapies

Treatment Center Platform (TCP)
Facing the patients & treatment centers

- **HCPs Interface** (eg treatment ordering forms)
- Support the **Patient Operations teams**, therapy certificate management and therapy access control
- Central entry point for all patient personal and **protected health data**
- Registration and submission of **patient blood and tissue samples**
- **Patient outcome documentation** and outcome based pricing milestone reporting
- System internal **Chain of Custody (CoC)** and **Chain of identity (Col)**, CoC/Col event report to TMP
- **Training and support material**, document management integration, **support interface** for HCPs

**Objective for the TCP** is to establish a standard industry wide portal that simplifies the engagement and relationship between life science & Biotech companies, treatment centers and patients.

Treatment Management Platform (TMP)
Supply chain facing capability to manage & facilitate the supply chain

- **Process facilitation** of TCP, TMP and core ERP transactions to enable rapid execution of the flow of goods, flow of funds, flow of documents.
- Enablement of **kit personalization and label printing** with patient data for single identified patient delivery
- Support new pricing and **risk sharing models for market access** by capturing the **outcomes based reimbursement** plan to trigger ERP transactions
- **Chain of Custody (CoC)** and **Chain of identity (Col)** consolidating TCP, ERP, logger data to create **end-to-end** audit capabilities
- **Slot scheduling** for individualized therapies, **capacity / stock confirmation** and reservation for GTs
- **Manufacturing integration** in case of in-house production
- Courier, Lab and CMO collaboration and organization

**TMP’s role is to facilitate, manage and drive the CGT supply chain to ensure the patient orders are fulfilled effectively. The TMP is the hyperconnected conduit between all functions in the supply chain ensuring flow of information between TCP and SC service providers delivering the order on time with zero defects or errors.**

HCP=healthcare professional; GT=gene therapies; CMO=custom manufacturing organizations
Roche response to COVID-19
Roche IT infrastructure and capabilities to run the business as usual

**Service Desk**
Incidents Created

- Very moderate increase of incident for 1st line support.

**Remote Collaboration**
Meeting Duration (Hours)

- Increase by 200% of virtual meetings.

**Remote Collaboration**
Meet Participants

- Increase by 375% of Meet Participants.

**Non-VPN Apps**
Cloudflare / WAF enabled Apps

- 500+ additional enterprise systems available outside Roche network.

**Non-VPN Apps**
Cloudflare / WAF Connections

- Strong increase of users accessing Roche systems via Cloudflare.

**VPN Connectivity**
Users

- Strong initial increase of users accessing Roche systems via Pulse Secure.
Roche Information Solutions (RIS)
Bringing insights into action for better healthcare

Moritz Hartmann/ Global Head of Roche Information Solutions, Roche Diagnostics
Digitalization impacting our entire value chain

- Early R&D
- Clinical Development
- Regulatory & Reimbursement
- Manufacturing & Distribution
- Commercialization
- Diagnosis
- Treatment Support Physicians & Patients
- Point of Care
- Digital Pathology
Roche Diagnostics platform products & business models

We provide platforms that power products across digital healthcare ecosystem

Third-Party Applications

Roche Applications & Algorithms

SaaS

App Marketplace

PaaS

* in development
Point of Care ecosystem

Making truly decentralized testing a reality with cobas infinity edge suite
Point of Care ecosystem
Opportunity for Roche to disrupt healthcare

cobas® pulse
Utilisation of cobas pulse as a smart medical device

&

cobas® infinity edge SMART
Enabling decentralized testing throughout the patient journey

3rd Party Apps

- Clinical decision support
- Communication / documentation
- Offline test entry
- Digital biomarkers
- Vital Signs*
- Sensor reader*

* in development
Point of Care ecosystem

Moving to cloud with cobas® infinity edge suite for seamless experience and secure connection to community-based POC devices

**UNITE**
- Connects primary care POC devices to cobas infinity POC in the hospital
- Launched January 31st 2020

**SCRIBE**
- Seamless integration of POC results into customer EMR systems
- Launched June 10th 2020

**SMART**
- Remote services for installation, registration, software and lot distribution
- Coming soon (Dec. 2021)

**FUTURE VALUE SERVICES**
- Flu heat maps, public health reporting, payor insights etc.

“Managing test results, monitoring irregular events and connecting with POC colleagues from anywhere is easy and shifts the focus away from administrative tasks to patient care.”

“Automatically transferring data between community-based POC devices and 3rd party EMRs helps manage data and other relevant information safely and securely.”

“Serviceability for software updates, third-party applications and remote access and service such as device registration is easy to use.”

“Digital tools to help extract insights that facilitate data-driven decisions with an impact for the broader population and public health.”

POC=point of care; EMR=electronic medical records
Providing powerful ecosystem of AI tools to pathologists

Digital Pathology ecosystem - an integrated solution for pathology and clinical decision support

Whole Slide Scanner

<table>
<thead>
<tr>
<th>DP 200</th>
<th>DP 600 (2022)</th>
</tr>
</thead>
</table>

Platform & Software

Roche uPATH

NAVIFY Digital Pathology (cloud)

Applications

Roche

Breast Cancer Algorithms Panel¹²

3rd Party

PathAI IBEX

PHC Algorithms*

Multiplex*

H&E*

*In-development; AI=artificial intelligence; ¹ HER2 (4b5), Ki-67, ER, PR and HER2 Dual ISH algorithms; ² Will be seeking FDA clearance of Breast Panel algorithms with external clinical studies in 2022; PHC=personalized healthcare
Integrated oncology decision support
AI-enabled digital solutions for informed, efficient patient management

**NAVIFY® Digital Pathology PD-L1 Algorithm**
Interpretation of biomarker

**NAVIFY® Mutation Profiler**
Therapy options & clinical trials

**NAVIFY® Tumor Board**
Radiology, pathology & clinical data together

**Flatiron and Foundation Medicine**
Access to clinico-genomics database

Quick, accurate answers for patients
Confident decisions & standardized care
Q&A
Doing now what patients need next