



RNA AI Enabled Platform for Next Generation Cures

By analyzing **RNA** we can monitor **health**, detect **disease** and design next generation **cures**

Company Stage: Commercial

Regulatory: CLIA and FDA EUA on COVID-19 PCR Test

Patents: Patents pending, trademarks and trade secrets, proprietary algorithms

Website:
genomicexpression.com

Product Video: <http://bit.ly/OneRNAMovie>

Literature: Clinical RNA sequencing in oncology: where are we? <http://bit.ly/ClinicalRNAseq>

Poster NYAS mRNA vaccine <http://bit.ly/NYASOneRNA>

Poster SITC OneRNA and AI <https://bit.ly/SITC2021OneRNA>

Poster NYAS Patient case with outcome data <https://bit.ly/OneRNA2022NYAS>

Grants:

- Danish Innovation Fund
- Eurostars
- Horizon2020

Partners:



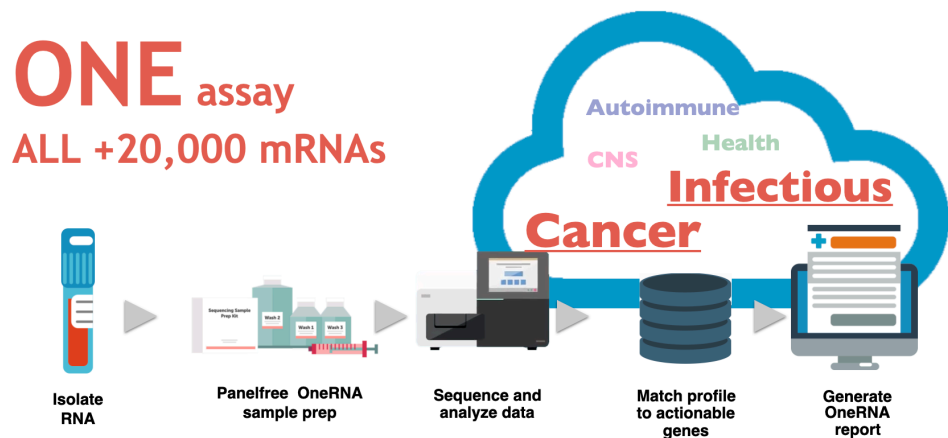
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Clinically validated RNA-sequencing analyzed on proprietary cloud based, HIPAA and GDPR compliant bioinformatics platform overcoming the two main hurdles of performing RNA sequencing in the clinic: A) RNA fragmentation and cross linking in FFPE samples and B) Making clinical decisions based on ONE patient sample - by comparing to true normal expression levels in sample type:

- 1) Provide patients with actionable treatment options and clinical trials
- 2) Follow response in a liquid biopsy sample taken at home
- 3) Expand drug label for approved oncology drugs
- 4) Rational design combination umbrella or basket trials addressing significant patient populations
- 5) Stratify patients into trial arms based on unlimited number of markers
- 6) De-risking clinical programs by develop companion diagnostics/response algorithms instead of relying on single markers
- 7) Design next generation truly individualized cancer treatment

OneRNA® can get from sample to report in less than a week and works with FFPE, FF, blood, urine, saliva.

The OneRNA® analytics platform can also use standard RNA sequencing data as input data to generate an actionable report



OneRNA® Report: from Sample to Actionable Report

Shipping kit: Preserves RNA at ambient temperatures so it can be shipped, saliva, urine, stool enabling decentralized clinical studies

Sample preparation method validated in FFPE, FF, blood, saliva, urine: The OneRNA® chemistry is optimized to produce robust and reproducible quantitative sequencing data from real patient samples e.g. embedded in FFPE and accurately identify and quantify +20,000 human transcripts for sequencing on Illumina platforms. Can also detect 1 RNA e.g. COVID19 in very large number of samples which can easily be multiplexed for large panels.

Bioinformatics: Generation of expression profiles from raw sequencing data using proprietary normalization algorithms to enable robust data across sequencing runs, sample types and labs HIPAA and GDPR compliant.

Database of actionable expression biomarkers: Contains drug targets and gene expression signatures linked to cancer therapies in clinical trials including all immune therapy targets.

OneRNA® report: A clinically actionable report that includes significantly overexpressed and underexpressed cancer drug targets including novel immune therapy targets, and expression biomarkers used in the clinic and clinical trials.

Platform for Next Generation Diagnostics and Cures

Designing combinatorial clinical studies that enroll meaning full eg +20% of a patient population here TNBC patients combining 1 checkpoint inhibitor with 3 different Tumor Antigen e.g. in the form of a vaccine.



Actionability compared to DNA sequencing

DNA panels such as the ones from Foundation Medicine are limited to cancer and typically identify one actionable marker in 80% of the patients which in the late stage setting where they are used translates into better outcome for 16% of the patients. OneRNA® identify typically 5 markets in 100% of the patients and that is a promise for improved outcome for most patients.

Opportunity for Pharma: 1) Expand the label and IP protection for existing drugs 2) Assist in the development of effective clinical strategies 3) Increase enrollment into clinical studies 4) Design next generation cures.

Clinical Programs: Data from breast cancer published in 2021. COVID-19 test FDA EUA self collection in saliva. Ability to leveraging the NGS platform to massively scale ONE RNA eg COVID-19 to +50,000 tests/day.

OneRNA® is exponentially scalable - digitalizing biomarkers with AI : The assay is portable into other clinical indications with modifications to the OneRNA® cloud backend. This solves a key problem in bringing clinical relevant markers into clinical practice by adding clinical relevant markers to the report without having to revalidate the assay.

Background: Genomic Expression was the diagnostic partner in Denmark’s first large sequence based project called “Genome Denmark”. The project was funded by the Danish Innovation Fund with \$32 million. The OneRNA® technology and vision was created as a result of this public private partnership.

Existing partnerships: [Rutgers Cancer Institute](#), [Nation Cancer Institute \(NCI\)](#), [The Danish Cancer Society](#), [The Val Skinner Foundation](#), [Yale/SalivaDirect](#)

Awards: #2in the Women’s Founders Pitch event, Top 10 companies to pitch for Sir Richard Branson (Virgin Airlines) Extreme Tech Challenge Top 5 diagnostic companies at the Molecular Tri-Conference, Top 100 on Red Herring list. Won the Lyfeybulb award and the EIC life science pitch competition. Presented at GSTIC, the UN and the European Commission. Semifinalist XPRIZE for Rapid COVID19 testing and finalist GuideWell for better COVID19 solutions.

Management team:

[Gitte Pedersen, CEO](#) is a former executive from Novo Nordisk, where she successfully developed and launched multiple products into multiple industries worldwide. She subsequently structured over \$1B in pharma deals with Merck, Takeda, GSK, Wyeth and others and was an advisor the Danish Government.

[Morten Pedersen](#) CSO, PhD is the inventor of GEx’s foundational technologies with a very strong innovation track record from Chr Hansen.

[Tanya Kanigan](#), CAO, post-doc from MIT, developed OpenArray®, spun it out into BioTrove which was later sold to Life Technologies. Diagnostic Big data AI.

[Jesper Zeuthen](#), CMO, PhD is the co-founder of GeneMap and DanDrit. He established the Danish Cancer Society and is a pioneer in immune oncology.

[Bill Southworth](#), VP Data, MIT, creator of products. CEO and Vice President of Engineering and Marketing for public and private companies. Coder at heart.

[Sugganth Daniel](#), Medical Director, MD, PhD, Foundation Medicine, Quest, Invitae.