



Real World Evidence as an investment

Capturing value at scale

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Почему мы проводим этот вебинар



1 Внимание к RWE растет

2 Мало информации на тему инвестиций в RWE

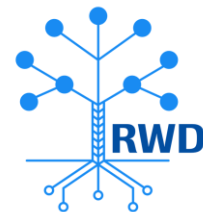
3 Подход к RWE как к инвестиции может принести пользу системе здравоохранения, в центре которой пациент

4 Необходимо участие всех участников системы здравоохранения

В настоящий момент нет единого трактования термина «ИНВЕСТИЦИЯ»

Терминология

- ✓ **Инвестиция** (От лат. investire – облачать) – денежные средства, ..., иное имущество, ... вкладываемые в объекты предпринимательской ... деятельности в целях получения прибыли и (или) достижения иного полезного эффекта¹
- ✓ **Инвестиции** – это любые ... средства, призванные служить удовлетворению будущих потребностей, для чего они отвлекаются от текущего использования и вкладываются в ... направление, приносящее выгоду²
- ✓ **Инвестирование** – это расходование в настоящем денежных или других средств в ожидании получения будущих выгод³
- ✓ **Возврат на инвестиции (ROI)** – рентабельность, показатель окупаемости вложений. Е.g. ROI 30% = вложено \$100, вернулось \$130, прибыль \$30



Признаки инвестиций



Ожидание дохода



Определенный срок вложения



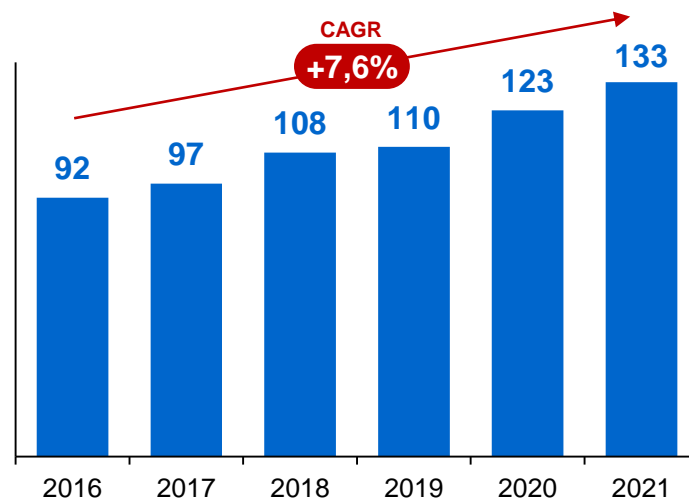
Уровень риска

Разработка препаратов (R&D) является примером длительно существующего инвестиционного механизма в фарм индустрии

- ✓ In 2021, the top 15 largest pharma companies invested \$133 billion in R&D expenditure (7.6% CAGR from 2016)
- ✓ Of the total global R&D investment, 44% is allocated for Phase I–III clinical trials, 27% dedicated to Phase III
- ✓ Cost was not identified as a top criteria for country selection. The pressure for fast-speed and quality trials drives the final decisions

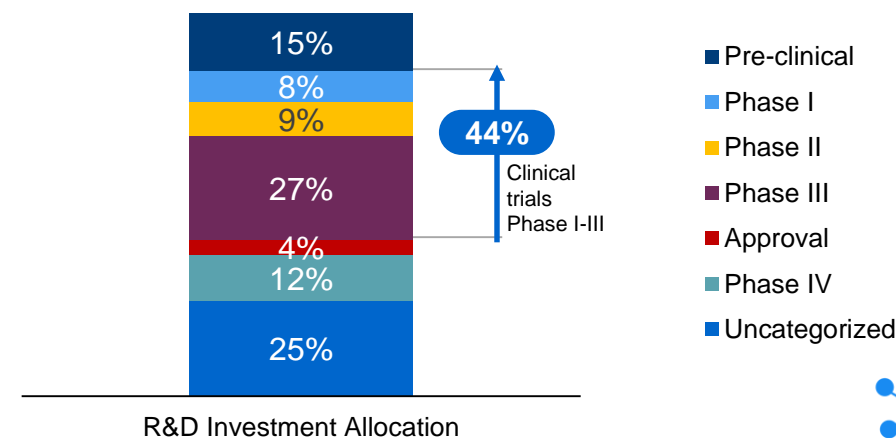


Top 15 large pharma R&D spending, 2016–2021, US \$Bn

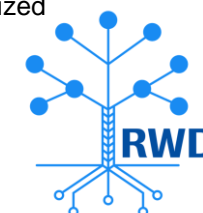


Source: IQVIA Institute R&D Trends 2022

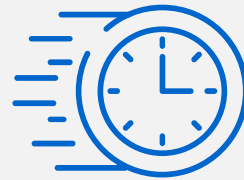
R&D by Function in PhRMA member companies, 2020, %



Source: Pharmaceutical Research and Manufacturers of America, PhRMA Annual Membership Survey, 2021.



Почему скорость так важна



Every additional week spent getting to market accounts for a loss of US\$300,000 in sales¹

There's a shift in focus for the early use of RWE in the product life cycle²

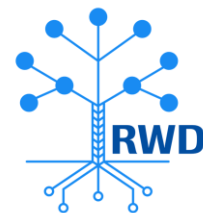
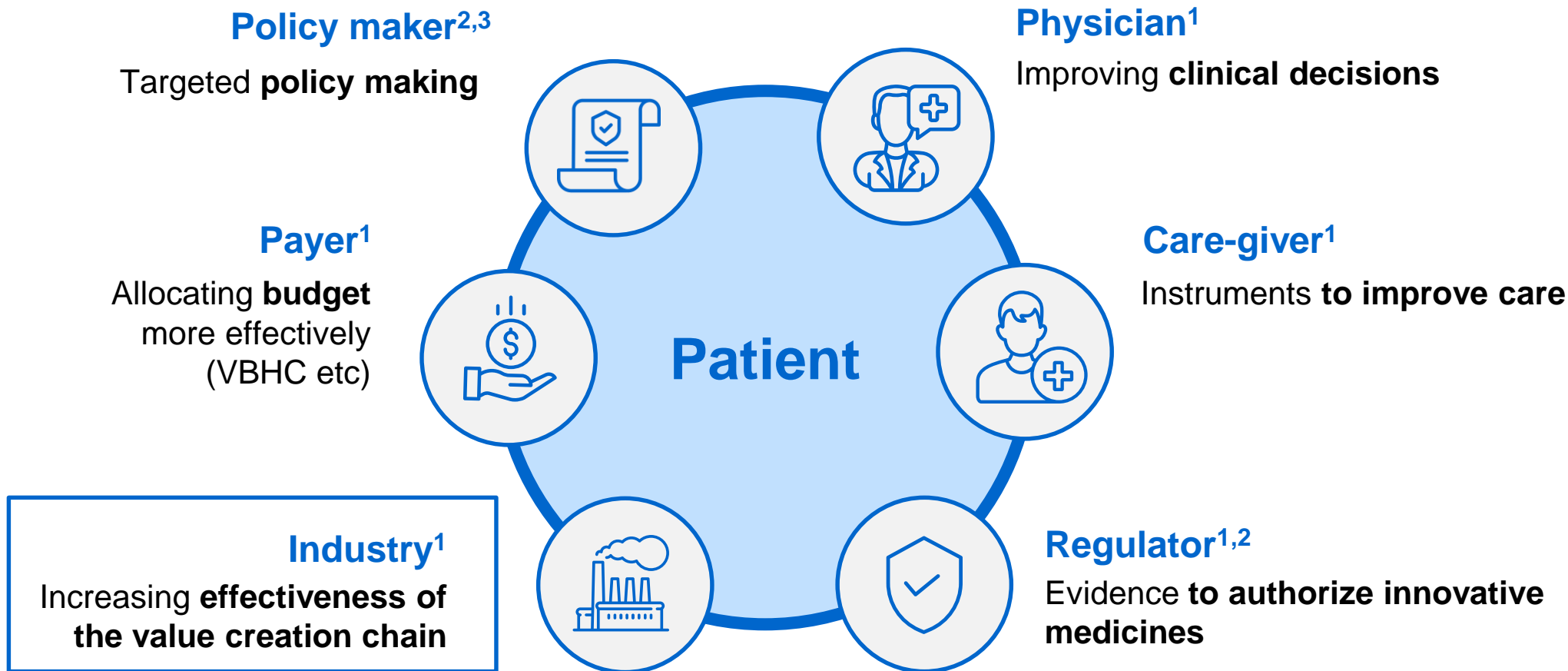


1. Paton J, Lauerma J. Big Pharma's drug studies are getting a NASA-style makeover. Bloomberg (2019). <https://www.bloomberg.com/news/articles/2019-01-25/big-pharma-s-drug-studies-are-getting-a-nasa-style-makeover>. 2. Olson MS Can real-world evidence save pharma US\$1 billion per year? / Journal of comparative effectiveness research / 2019- <https://pubmed.ncbi.nlm.nih.gov/31774337/>

Real World Evidence тоже является инвестицией и «питает» ценностно-ориентированный подход в здравоохранении



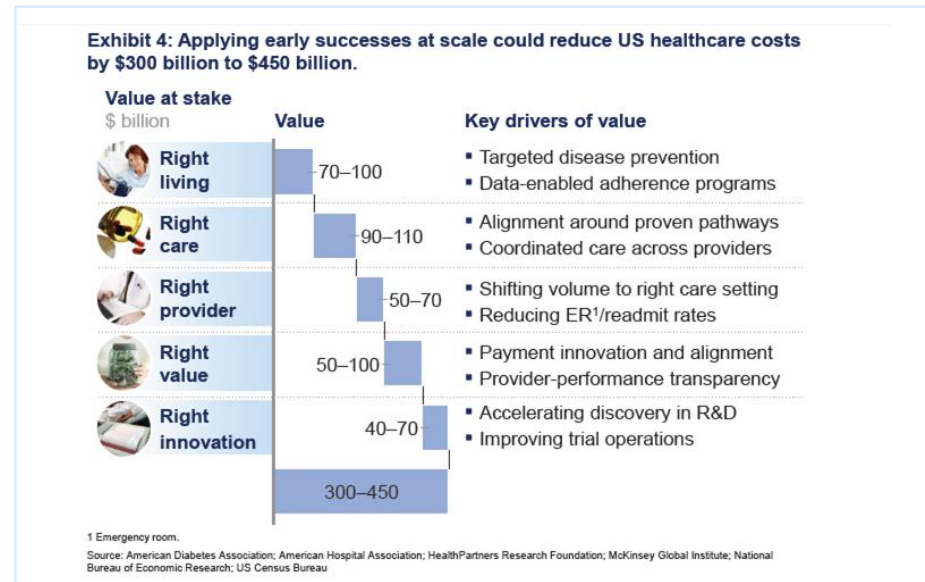
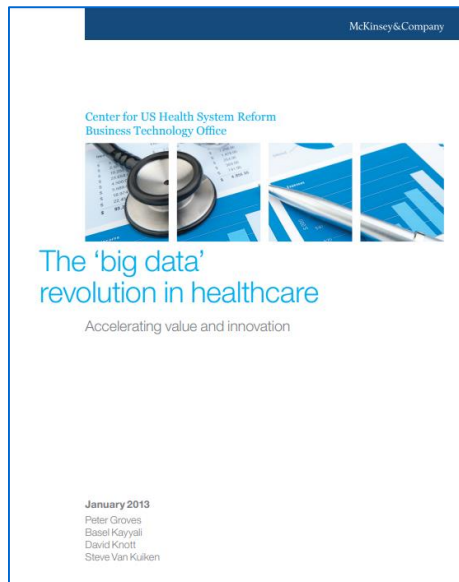
Социальная значимость Real World Evidence



Ценностно – ориентированный подход позволяет снизить затраты в системе здравоохранения США на 12-17%

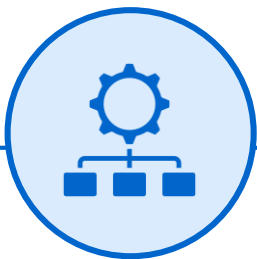


- The new value pathways are: right living, care, provider, value, innovation
- Value is derived from the balance of healthcare spend (cost) and patient impact (outcomes)
- The pathways could account for \$300bn to \$450 bn reduced healthcare spend in US healthcare costs



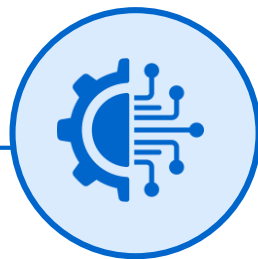
1. McKinsey & Co. The "big data" revolution in healthcare, 2013 - https://www.mckinsey.com/~media/mckinsey/industries/healthcare%20systems%20and%20services/our%20insights/the%20big%20data%20revolution%20in%20us%20health%20care/the_big_data_revolution_in_healthcare.pdf

Примеры инвестиций в RWE



Инфраструктура
и доступ к данным

[BD4BO](#)
[EHDEN](#)



Технологии¹



Проведение RWE
исследования



Люди (capabilities,
employees,
operating model,
etc)²










Фарминдустрия использует RWE по всему жизненному циклу продукта для создания ценности

RWD prize of \$4 billion to seize over 3 years globally¹

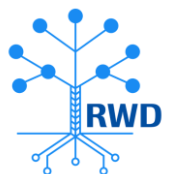
Cost

Revenue




Function	Examples of use cases	Level	Impact examples	Cost	Revenue
 R&D	<ul style="list-style-type: none"> Unmet need and targets for product development Clinical trial design and execution 	GLOBAL	Cost reduction, faster launch	\$500 m	\$1250 m
 REGULATORY	<ul style="list-style-type: none"> Filing new molecules, label extensions Post-marketing surveillance, eliminate need for a trial / study 	GLOBAL AND LOCAL	Cost reduction, faster launch	\$300 m	\$300 m
 CLINICAL PRACTICE	Scientific excellence: <ul style="list-style-type: none"> Epidemiology Care pathways Long-term outcomes 	LOCAL	Earlier uptake, bigger patient pool	\$300 m	
 MARKET ACCESS	<ul style="list-style-type: none"> Improve evidence of economic value Comparative effectiveness Value-based contracts 	LOCAL	Earlier access, uplift in sales	\$750 m	
 COMMERCIAL	Internal strategic and operational decisions, commercial precision	LOCAL	Cost reduction, uplift in sales	\$100 m	\$500 m

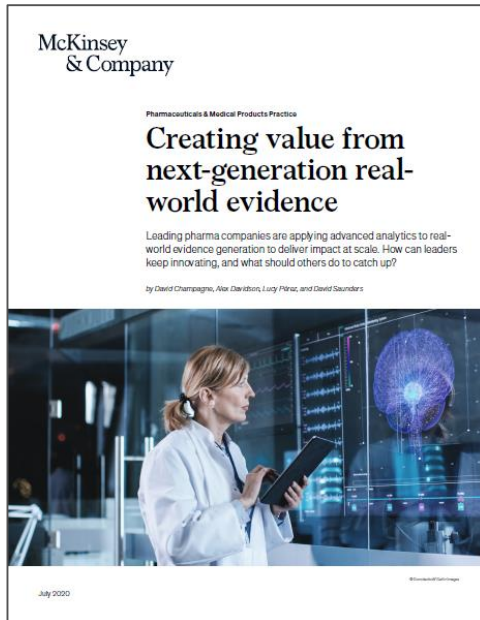
Advanced analytics, AIML (Artificial Intelligence & Machine Learning) or predictive modeling can be leveraged across all types of usage

1. IQVIA White Paper "Capturing Value at Scale: The \$4 billion RWE Imperative", 2021. Source: IQVIA Thought Leadership. Includes both accelerated and incremental revenue. Selected levers, applied to typical addressable big pharma cost / revenue base; derived from IQVIA proof points of observed impact



Advanced RWE аналитика позволяет увеличивать возврат на инвестиции как на до-, так и пострегистрационном этапе

-  Advanced RWE analytics uses predictive models to extract deeper insights
-  It gives additional opportunities to derive value which traditional analytics can't offer
-  A top-20 pharmaco could unlock >\$300 mln a year over next 3-5 years by adopting advanced RWE analytics across its value chain:



R&D cost saving of \$100 million via:

- Optimization of RCT design
- Use of RWE studies rather than RCTs
- Implementation of synthetic trial arms

Revenue generation of \$200 million via:

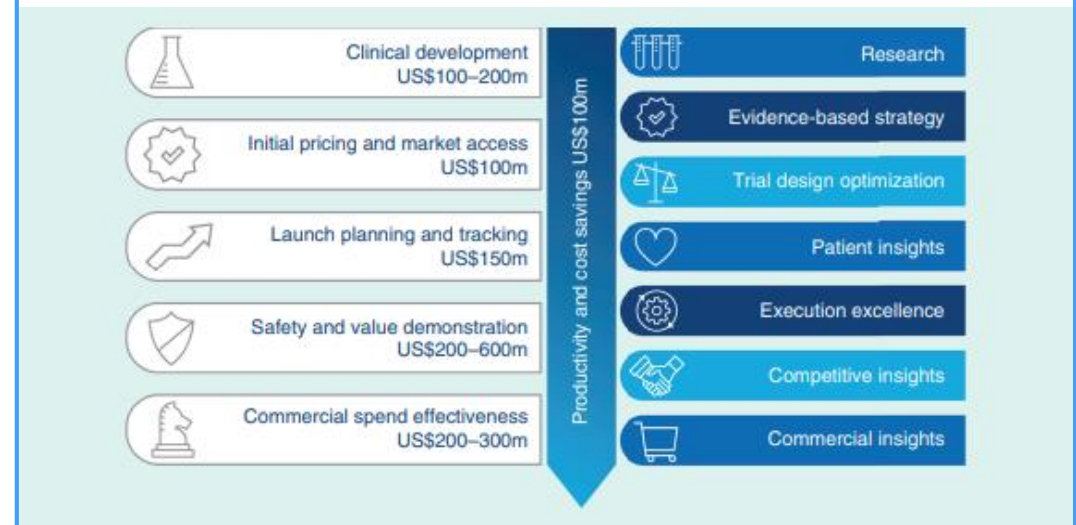
- Identification of new targets for molecules
- Time to market acceleration
- Improved formulary position and payer negotiations
- Stronger evidence of differentiation



Evidence-powered operating framework may be associated with significant efficiency savings for pharma

- ✔ Integrated evidence generation strategy is a must
- ✔ Framework (EPOF) enables strategy implementation
- ✔ Framework use case example: early feasibility analysis

QuintilesIMS (now IQVIA) –projected cost measures mapped against EPOF pillars^{1,2}



A company that captures \$1 billion in RWE value for itself ultimately creates improvements in the healthcare system valued in the tens of billions of dollars



RWE return calculation: mission critical

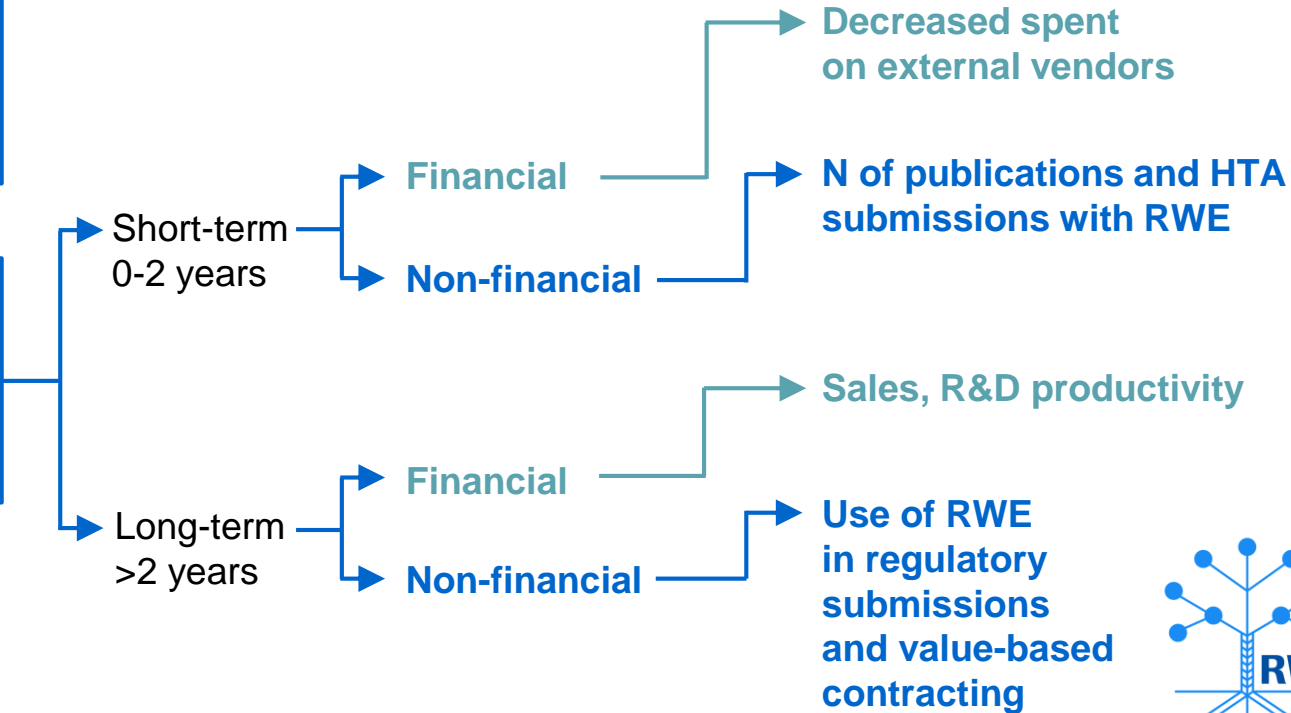


1 Companies are making RWE investments across the product life cycle in the hope of achieving cost savings and efficiencies

2 Investments are made in people, data and technology (including machine learning)

3 There's a bunch of experimenting with financial and non-financial metrics for short- and long-term return

Metrics for RWE ROI calculation



1. Deloitte Insights. Mission critical: biopharma companies are accelerating real-world evidence adoption, investment, and application (2018)

Take-away messages



Real World Evidence is an investment tool with a societal and financial value



As any investment, RWE can be characterized by a certain ROI



ROI is an important consideration for investing in any RWE dimension



There are difficulties assessing ROI in RWE studies that should be taken into account in planning and conduct



Acknowledgements



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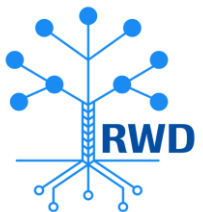
**Евгения
Новодережкина**

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AIPM по RWE



**Анастасия
Моргунова**

МВА, член рабочей
группы AIPM



Doing now what patients need next