BIONICAL

orld Evidence in
ded Access

are we here?

t can RWE achieve?

examples

ing Patient Outcomes

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hy are we here?

ient demand for earlier access to medicines

tory of incentives in Expanded Access

ulatory framework for RWE

hnology

ing Patient Outcomes

FDANEWS/ Cent

gulatory Framework

e 21st Century Cures Act requires the FDA to establish a draft
mework for combining Real World Data and regulatory science
7 FDA issued final guidance on use of RWD within medical devices
ropean Medicines Agency provided initial RWD guidance – post
thorization

hat can Real World Evidence achieve?

ter approval times?

er label?

re accurate label?

cover new research directions?

ablish what really works (and what does not)?

in reimbursement?

order to achieve this we must:

clear on how dataset was created

rify cohort selection

rify how we analyze data

rify how we weight and match comparison groups

t we must get on with it and get things done…….

rly examples

ord lung study

iron Health

le

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nded Access?

est of the sick

resort

ty events

en of disease

firmatory data for reimbursement

disease

ing Patient Outcomes

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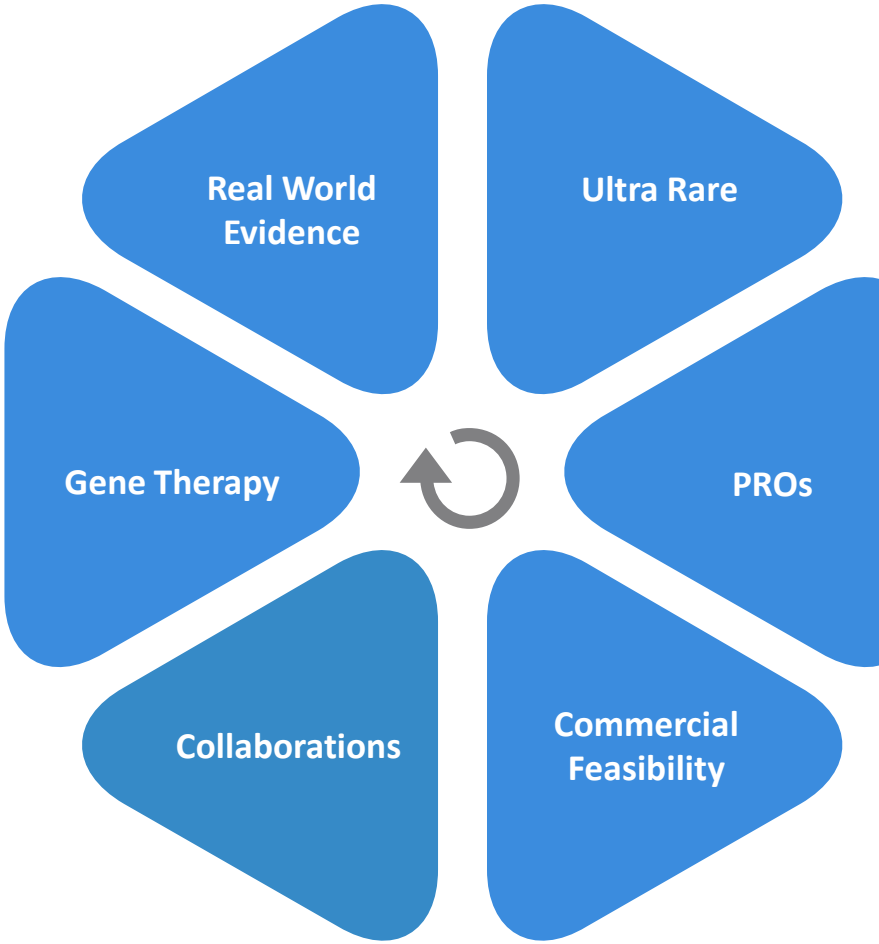
exciting future challenges



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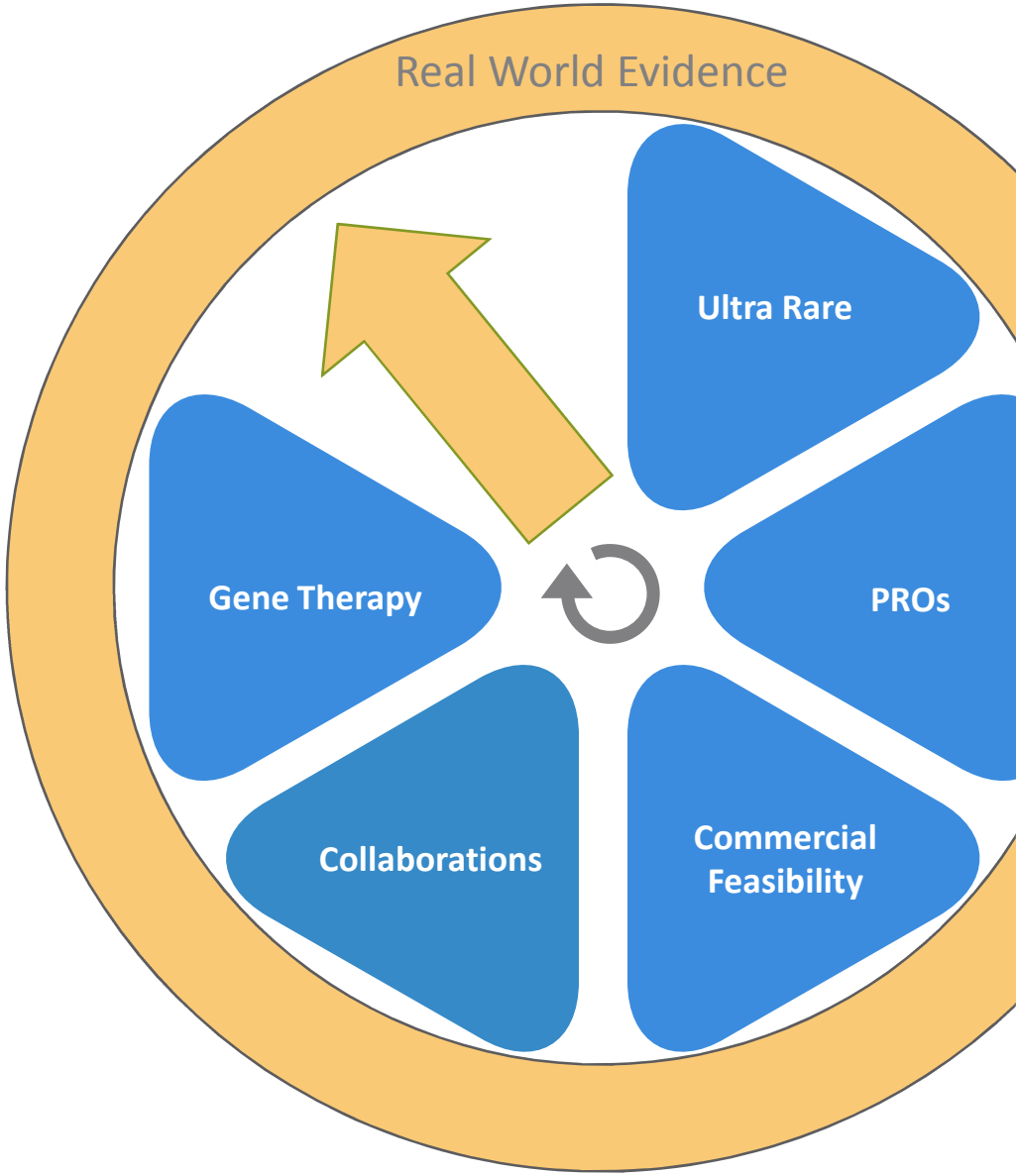
w paradigm for Early Access



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