Five Data-Informed Principles for Advancing Inclusive Research in Clinical Trials: A Pharma Perspective

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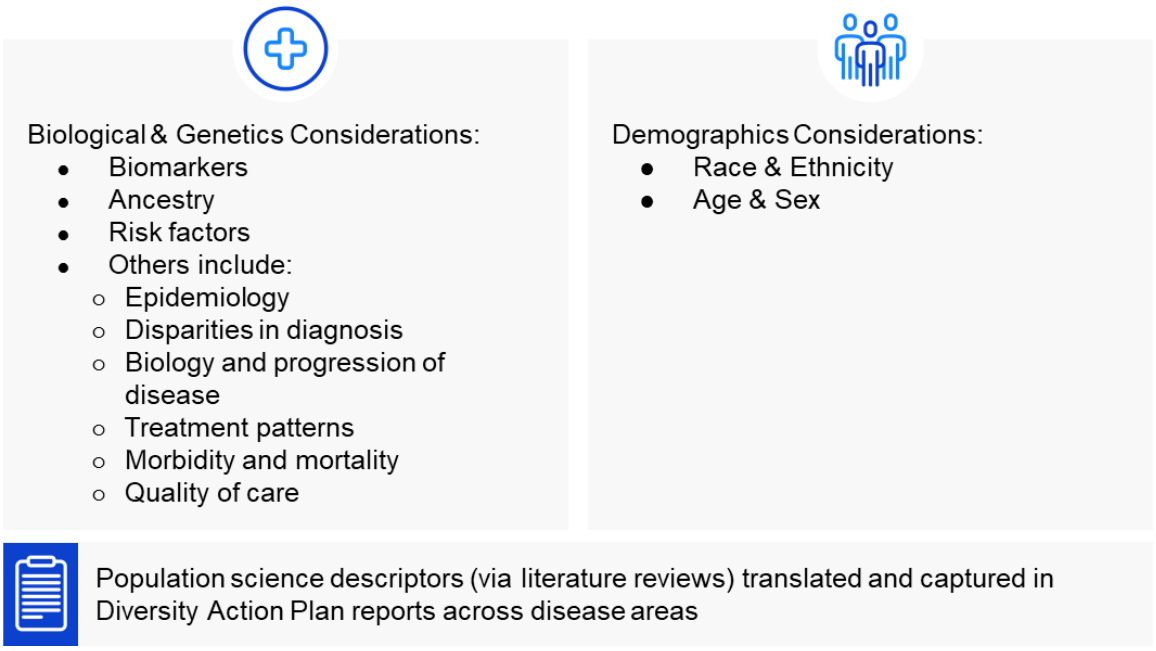
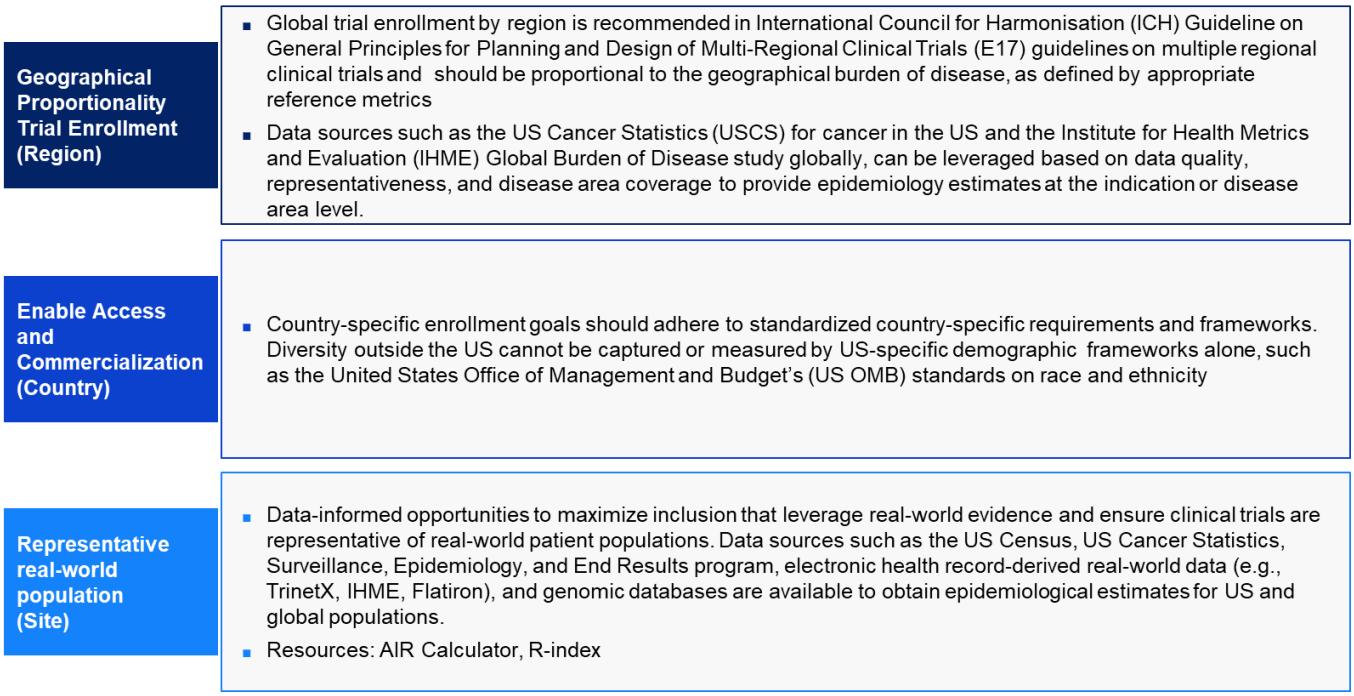
SUPPLEMENT

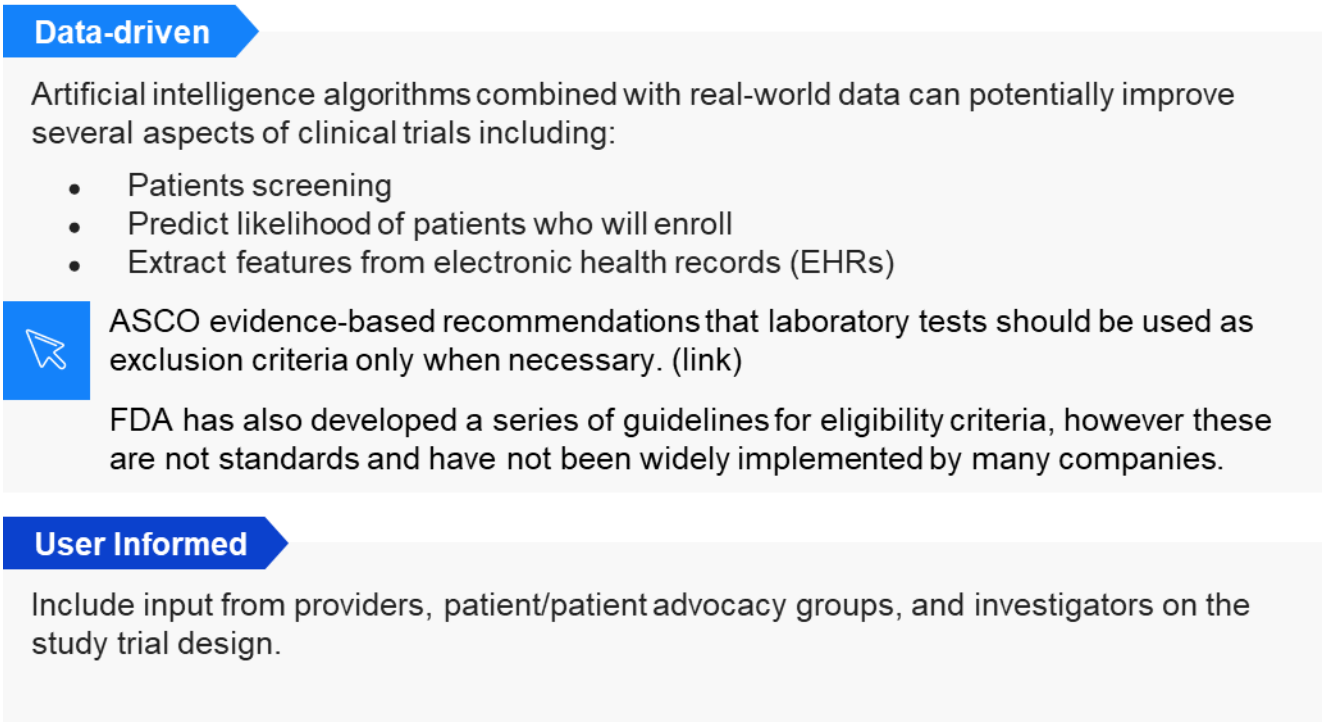
Supplemental Figure 1. Principle 1: Population science considerations. WHO is the population most affected by the disease or condition?



Supplemental Figure 2. Principle 2: Data-informed country and site placement. WHERE are the patients?



Supplemental Figure 3. Principle 3. End-to-end inclusive trial design. WHAT is the trial design? ASCO, American Society of Clinical Oncology; FDA, Food and Drug Administration.



Supplemental Figure 4. Principle 4: Patient-reported data collection standards. WHO are the individual patients participating? (A) standardized electronic case report form (eCRF) to Food and Drug Administration/Office of Management and Budget (FDA/OMB) race categories (B) social determinants of health (SDOH) questionnaire (C) sexual orientation gender identity (SOGI) data collection fields according to the Clinical Data Interchange Standards Consortium (https://www.cdisc.org/kb/ecrf/sexual-orientation-gender-identity-sogi)

A

Race Grouping	Race Sub-category	Mapping (to FDA guidance)
ALASKA NATIVE OR AMERICAN INDIAN	North American Indian Or Alaska Native	American Indian Or Alaska Native
	Central American Indian	American Indian Or Alaska Native
	South American Indian	American Indian Or Alaska Native
	Other Indigenous Not Listed	American Indian Or Alaska Native
ASIAN	Chinese	Asian
	Filipino	Asian
	Japanese	Asian
	Korean	Asian
	South Asian	Asian
	Vietnamese	Asian
	Other Asian Not Listed	Asian
BLACK	African American	Black Or African American
	African Caribbean	Black Or African American
	Black African	Black Or African American
	Other Black Identity Not Listed	Black Or African American
INDIGENOUS AUSTRALIAN OR PACIFIC ISLANDER	Aboriginal Or Torres Strait Islander	Native Hawaiian Or Other Pacific Islander
	Maori	Native Hawaiian Or Other Pacific Islander
	Native Hawaiian	Native Hawaiian Or Other Pacific Islander
	Other Pacific Islander Not Listed	Native Hawaiian Or Other Pacific Islander
MIDDLE EASTERN, NORTH AFRICAN, OR WHITE	Middle Eastern	White
	North African	White
	White	White
–	Unknown	Unknown

B

Education

What is your level of education/schooling?

[ ] Elementary School
[ ] Middle School
[ ] Some High School
[ ] Graduated from High School
[ ] Some College
[ ] Graduated from College
[ ] Post-Graduate

Income Status

What is your annual household income?

[ ] < $15,000
[ ] $15,000 - $34,999
[ ] $35,000 - $49,999
[ ] $50,000 - $74,999
[ ] $75,000- $99,999
[ ] $100,000 - $149,999
[ ] >$150,000

Employment Status

Before your diagnosis, what was your employment status?

[ ] Full-time Employed
[ ] Part-time Employed
[ ] Self-employed (either full-time or part-time)
[ ] Retired
[ ] Not employed

Marital Status

What is your marital status?

[ ] Single (never married)
[ ] Married (including common law)
[ ] Separated
[ ] Divorced
[ ] Widowed
[ ] Domestic Partnership (same sex, opposite sex or unregistered)

Health Insurance Status

What type of health insurance do you have, if any. Please select one:

[ ] Private/Commercial
[ ] Medicare
[ ] Medicaid
[ ] Veteran Affairs (VA) Health Plan
[ ] Other

[ ] I do not have a health insurance

Zip Code of Home Residence

What is the zip code of your home residence?

C

cdisc

Protocol Sexual Orientation and Gender Identity

Site Number | Subject Number

Sexual Orientation and Gender Identity

1 Sexual Orientation and Gender Identity

1.1	Was SOGI (Sexual Orientation and Gender Identity) data collected?	○ Yes SCPERF ○ No
1.2	What [is/was] the date of the collection? (DD-MM-YYYY)	SCDAT SCDTC
1.3	What sex were you assigned at birth on your original birth certificate? (Check one):	○ Female SEXABRTH_SCORRES ○ Male SCORRES where SCTESTCD = "SEXABRTH" ○ Intersex ○ Not Reported
1.4	Were you born with a variation in your physical sex characteristics? (this is sometimes called being intersex or having a difference in sex development)?	○ Yes ISXDXIND_SCORRES ○ No SCORRES WHERE SCTESTCD = "ISXDXIND" ○ Unknown ○ Not Reported
1.5	What is your gender identity at this time? (Check all that apply):	○ Cisgender Woman/Girl ○ Cisgender Man/Boy ○ Transgender Woman/Girl ○ Transgender Man/Boy ○ Gender Queer ○ Gender Fluid ○ Non-Binary GENIDENT_SCORRES ○ Unknown SCORRES WHERE SCTESTCD = "GENIDENT" ○ Not Reported
1.6	Which of the following represents how you think of your sexual orientation at this time? (Check all that apply):	○ Lesbian SEXORIE_SCORRES ○ Gay SCORRES WHERE SCTESTCD = "SEXORIRS" ○ Straight or Heterosexual ○ Bisexual ○ Queer ○ Pansexual ○ Asexual ○ Aromantic ○ Unknown ○ Not Reported

Supplemental Figure 5. Enabling access to trials. HOW will patients access trials and treatment beyond trial completion?