



THE FUTURE OF VACCINE CLINICAL STUDIES IN CANADA

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I have no actual or potential conflict of interest in relation to this program.

{Or disclose any real or apparent conflict(s) of interest that may have a direct bearing on the subject matter of the program.}



OBJECTIVES

- Provide overview of vaccine studies and sponsorship
- Identify constraints for Canadian researchers
- Highlight opportunities for Canadian researchers
- View of near future for domestic vaccine studies



VACCINE DEVELOPMENT SEQUENCE (PIPELINE)

1. Development of the epidemiologic rationale
2. Development and pre-clinical testing of candidate vaccine
3. Pre-licensure trials (dosing, safety, efficacy)
4. Post-approval evaluations (safety, economics etc)
5. Immunization program support, evaluation



VACCINE RESEARCH OPPORTUNITIES

- Opportunities for academic and public health researchers to “get involved” are broad
- Differ among the steps of product development
- Changing over time as industry evolves
- Depend greatly on funding availability



EPIDEMIOLOGIC STUDIES: SCOPE

- **Classic**: incidence rate, age distribution, temporal trends, risk factors/groups, outcomes
- **Newer**: pathogen diversity and evolution, economic rationale, modeled program options, population receptivity
- **Scope**: national, provincial, other defined populations
- Also program evaluation: safety, effectiveness etc



EPIDEMIOLOGIC STUDIES: OPPORTUNITIES

- Home turf for population health, health services researchers
- Easiest for reportable infections requiring hospitalization
- Limited existing infrastructure, room for growth
- Limited funding for infrastructure development and research projects (CIHR, MOH's, NIS?, industry)



VACCINE DEVELOPMENT AND PRE-CLINICAL: SCOPE

- Insights into the basis of protective immunity
- Identifying protective, safe, widely applicable antigen(s)
- Evaluation in relevant animal model(s)
- Development of product formulation and manufacturing process



VACCINE DEVELOPMENT: OPPORTUNITIES

- Begins with basic scientists, biotech and larger firms
- Opportunities for microbiologists, immunologists, engineers
- Large companies monitor and acquire best prospects
- Funding: grants, contracts, venture capital, industry



PRE-LICENSURE CLINICAL TRIALS: SCOPE

- **Phase 1:** small scale safety and response studies (adults)
- **Phase 2:** numerous studies in many subjects to define dosing requirements, lot consistency, safety, immunogenicity, booster need etc
- **Phase 3:** definitive demonstration of efficacy, safety in a population at high disease risk (large N)



PRE-LICENSURE VACCINE TRIALS: OPPORTUNITIES

- Only large companies can fund the high cost of trials program
- Distribute trials among potential market countries with suitable trials infrastructure, competitive costs
- Licensing requirements also considered per country
- Sponsors favor home market (1st licensure approval)



VACCINE INDUSTRY TRENDS

- Canada's 2 domestic companies are now parts of international companies with HQ elsewhere
- We account for only ~1% of global vaccine purchases
- BGTD does not require studies to be done here if adequately done elsewhere and applicable locally



VACCINE TRIAL OPPORTUNITIES: SHRINKING

- Fewer with loss of Connaught and ID BioMedical (IAF) to multi-national companies
- Trend towards multi-country trial designs
- Stiff cost competition from emerging market countries
- Harmonization of licensure requirements is reducing overall trial numbers per product, with cost savings



VACCINE TRIAL OPPORTUNITIES: INFLUENCES

- Canada's 5 well-established trials centers remain “magnets” for industry studies
- Progressiveness of marketplace, regulator attractive
- Unique domestic issues remain (populations, programs)
- Growing funding options from CIHR, provincial MOH's but still limited overall
- Notable absence of National Imm Strategy sponsor



POST-LICENSURE STUDIES: SCOPE

- Phase 4, extended safety studies
- Compatibility studies - domestic
- Special populations e.g. First Nations
- Dosing modifications, e.g. 2 vs 3 doses
- Need for and timing of boosters



IMMUNIZATION PROGRAM EVALUATIONS: SCOPE

- Policy analysis
- Acceptance facilitation
- Uptake assessment and improvement
- Vaccine effectiveness assessment
- Ongoing safety evaluation



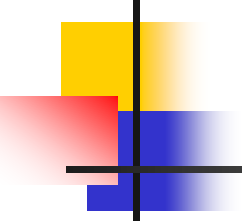
PROGRAM-RELATED STUDIES: OPPORTUNITIES

- Most needed, least developed area of vaccine research in Canada
- Priority growing with rising vaccine costs, program budgets
- Scope remains largely domestic (federal, provincial)
- Critical mass of expertise to drive funding agenda



LOOKING AHEAD AT STUDY PROSPECTS

- Vaccine discovery and early development: positive climate
- Vaccine clinical trials: at capacity, growth unlikely, need to sustain core network for pandemic preparedness etc
- **Program evaluation/research:** positive prospects, growing recognition of need to fund, nearing critical mass for area to mature and firmly establish itself but core funding mechanism needed (ideally within NIS)



QUESTIONS?