

The Site Perspective – Successes and Challenges

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The Site Perspective

Successes

1. specialty niche
2. multiple sites
3. patient registry
4. Best Workplace

Challenges

1. decline in good Canadian studies
2. missing national BD support
3. current payment systems

1. Specialty niche

LMC Specialist Program:

- 41 Endocrinologists & PA's
- >120K patients
- 24,000 new patients per year
- 6,000 active referring doctors

Diabetes Education Program

- 29 Certified Diabetes Educators

1. Speciality Niche

- Establish expert reputation
- Mitigate research cycles
- Facilitates broader scope of involvement
 - Planning & Advisory roles
 - Feasibility studies
 - Scientific Authorship

2. Multiple sites



2. Multiple sites



Ontario

- Toronto
- Etobicoke
- Thornhill
- Oakville
- Brampton
- Barrie
- Markham

Quebec

- Montréal

Alberta

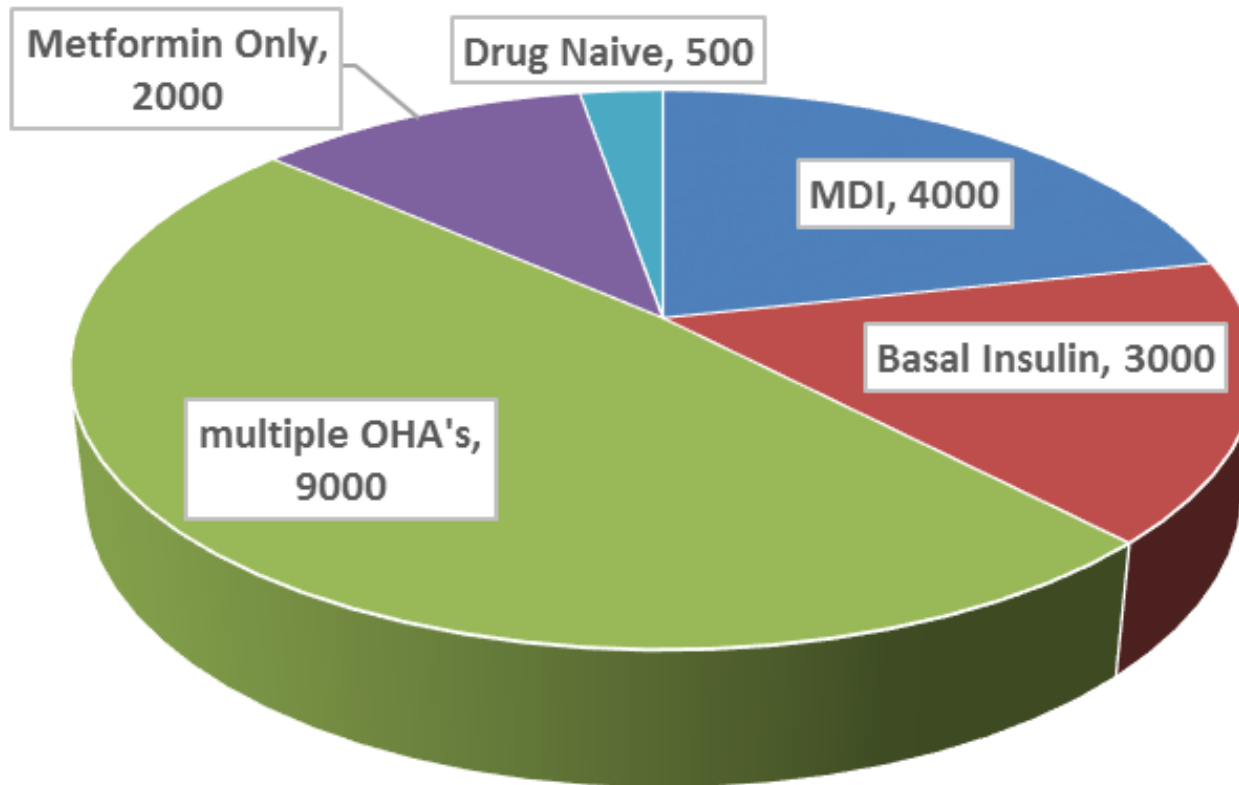
- Calgary

2. Multiple Sites

- Multiple investigators and their ...
 - whims
 - egos, competitiveness
 - research/scientific interest
- Strategize for population composition

3. Patient Registry

Type 2 Diabetes (n= 18,500)



■ MDI ■ Basal Insulin ■ multiple OHA's ■ Metformin Only ■ Drug Naive

3. Patient Registry

Diabetes - by co-morbidity

stage 3 CKD
(eGFR<60),
3,500

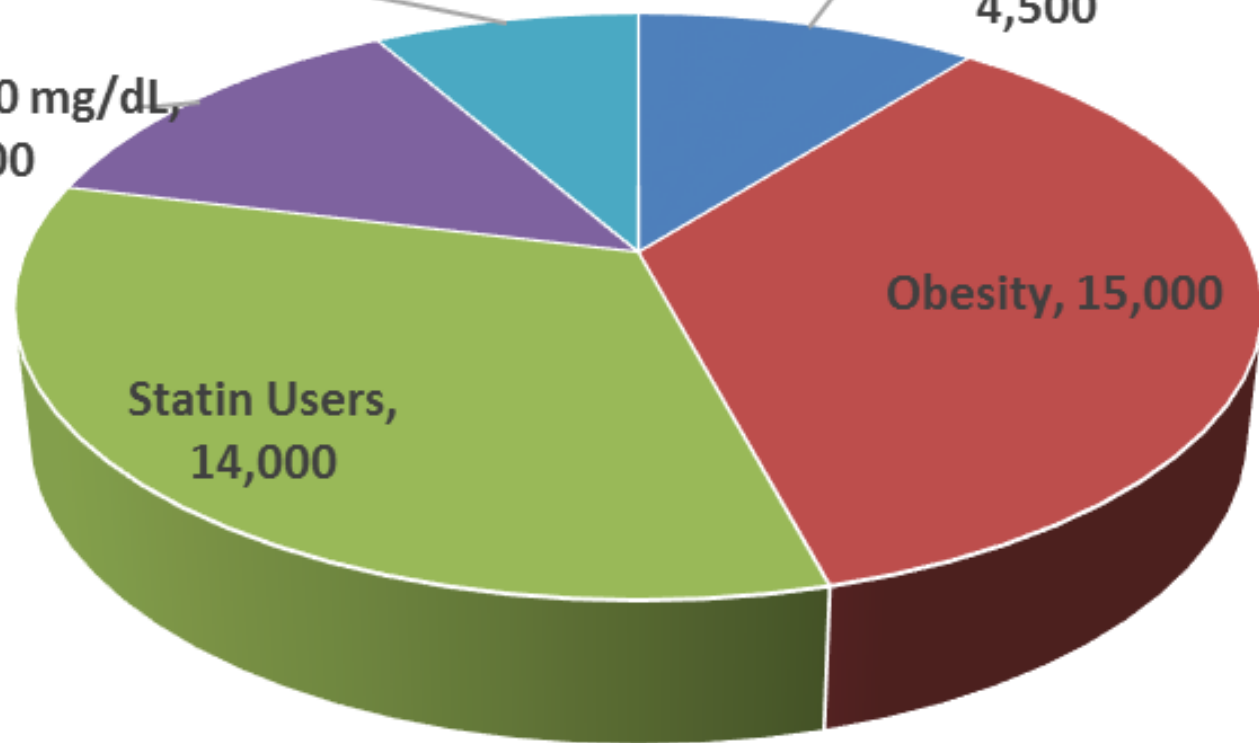
LDL-C > 100 mg/dL,
5,500

Osteoporosis,
4,500

Obesity, 15,000

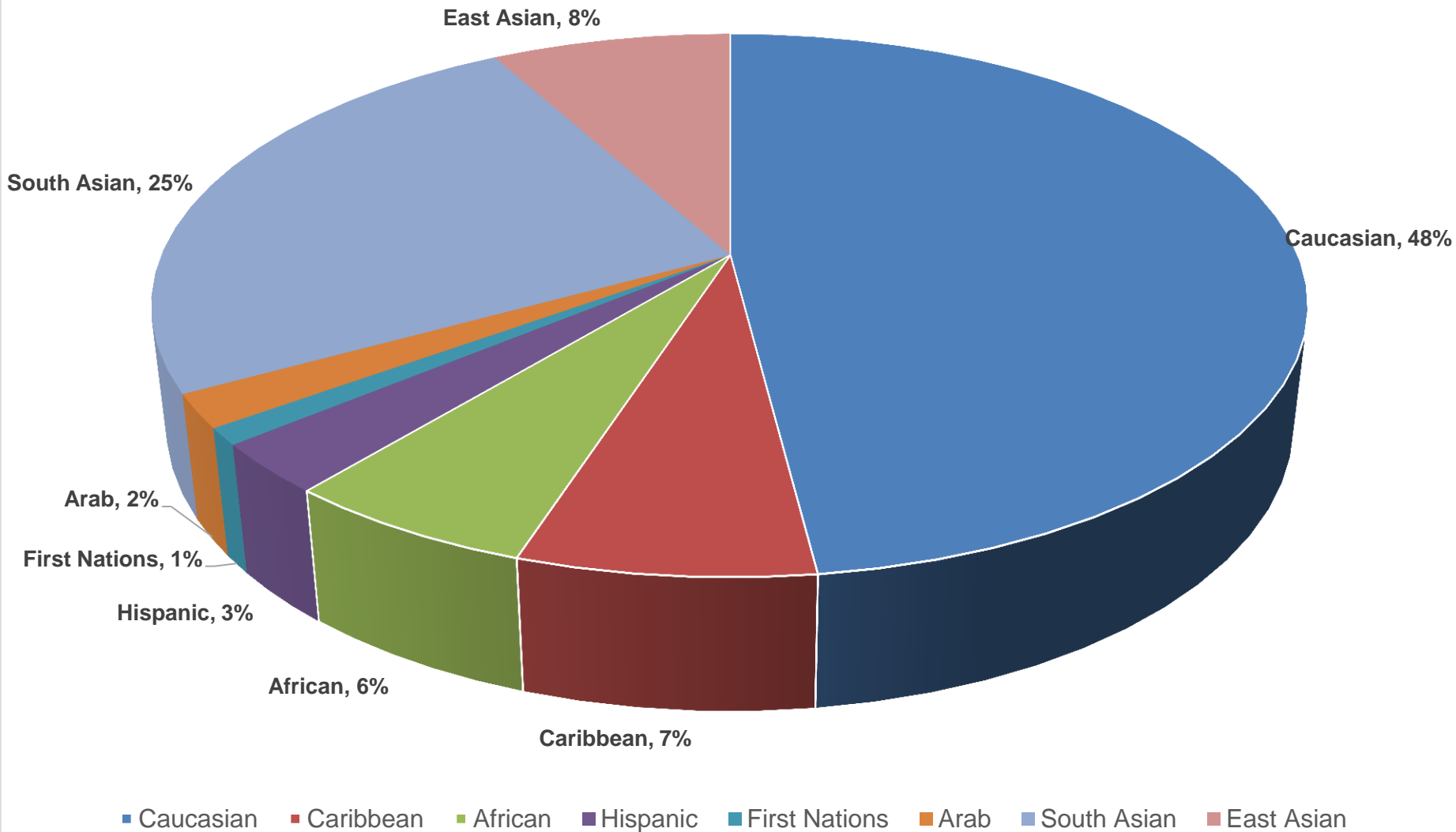
Statin Users,
14,000

- Osteoporosis
- Obesity
- Statin Users
- LDL-C > 100 mg/dL
- stage 3 CKD (eGFR<60)



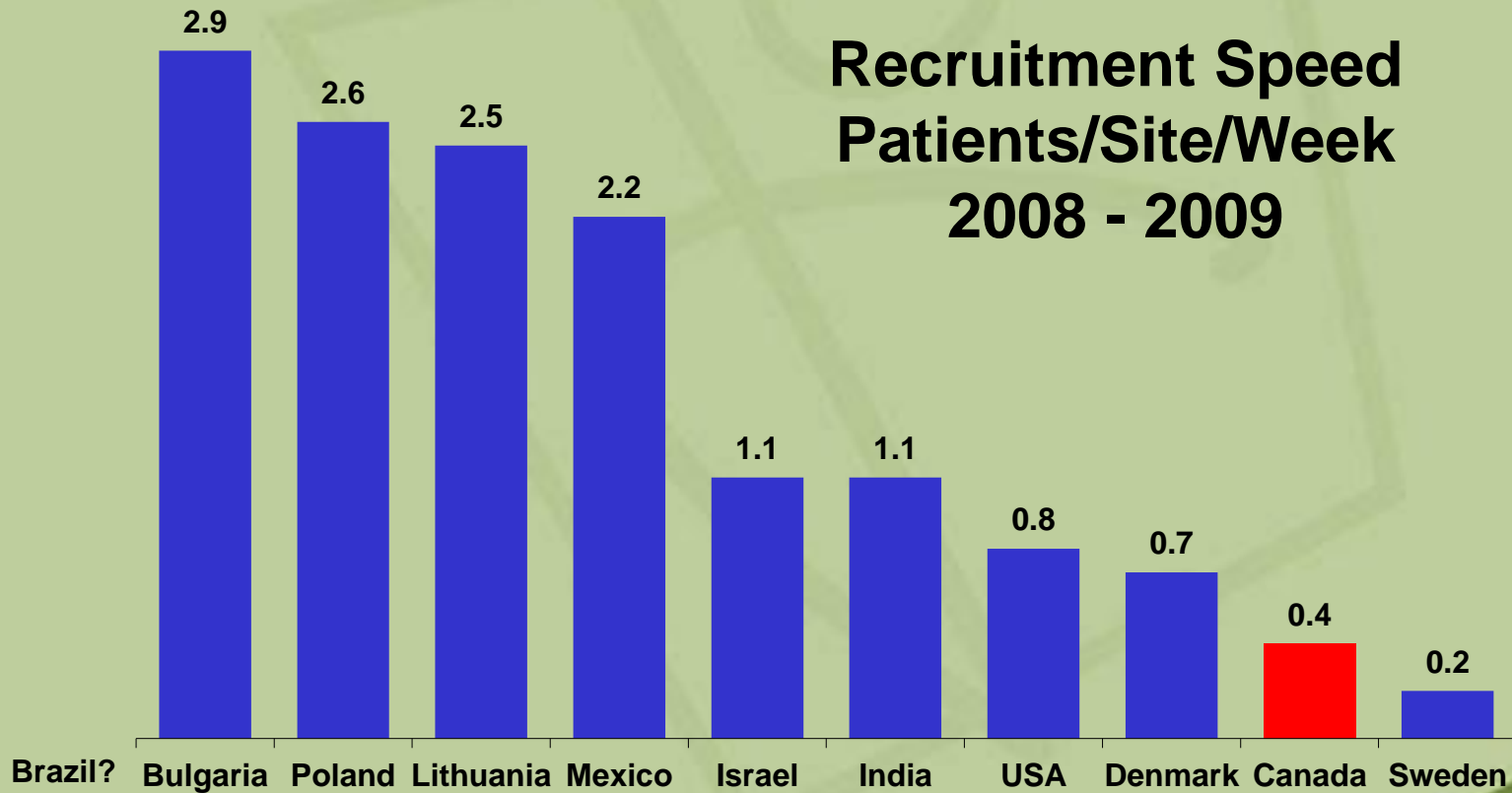
3. Patient Registry

Ethnic Diversity



Why is a Registry Important?

Recruitment Speed Patients/Site/Week 2008 - 2009



3. Patient Registry

- Brazilian our enrolment!
- inclusion/exclusion screening
- recruiter pool

Who will win the race?



Canadian FPFV

(First Patient First Visit)

2013 – 8

2014 - 6

DECLARE Study - Enrollment

Current Rank	Site	Country	Total Randomized	Randomized This Month	Previous Chart Position
1	Site 1047 (Dr. Ronald Goldenberg) LMC Diabetes and Endocrinology Thornhill	 Canada	146	0	1
2	Site 1045 (Dr. Harpreet Bajaj) LMC Diabetes and Endocrinology (Brampton)	 Canada	135	0	2
3	Site 1044 (Dr. Ronnie Aronson) LMC Diabetes and Endocrinology (Bayview)	 Canada	106	0	3

4. Best Workplace

Canada's Top 100 Best Workplaces

Ranked # 28 (Medium Size)

Ranked #17 (Best Workplaces – Women)



The Site Perspective

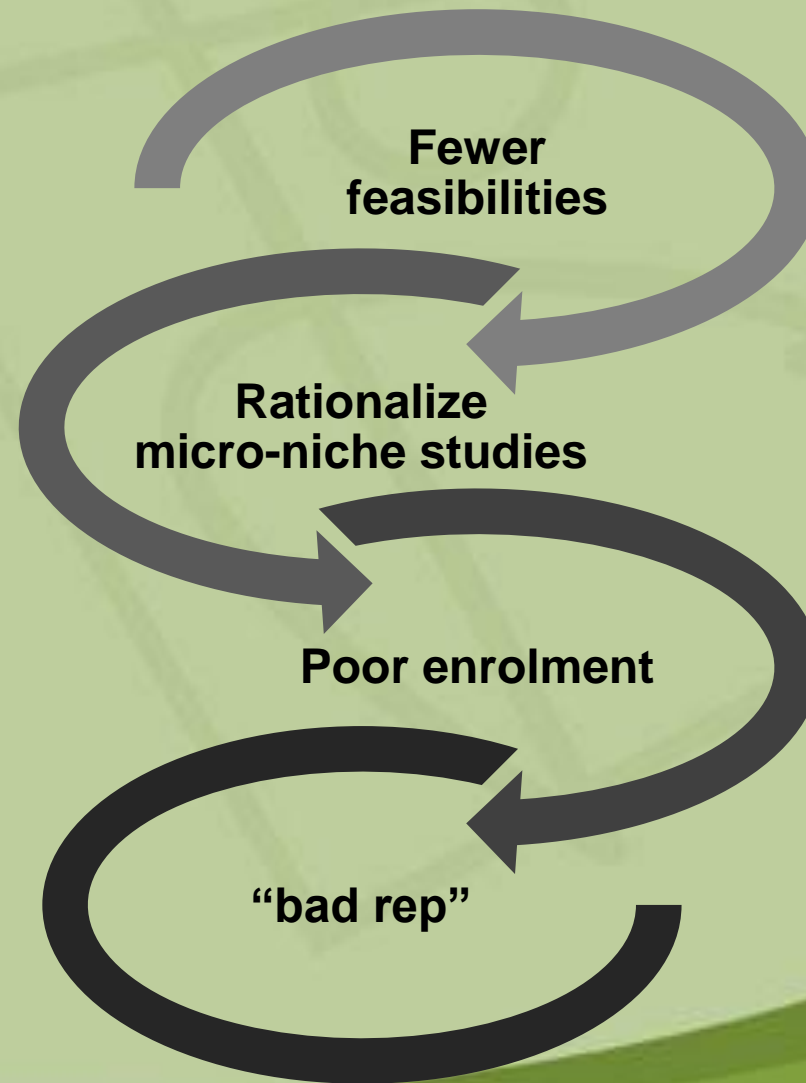
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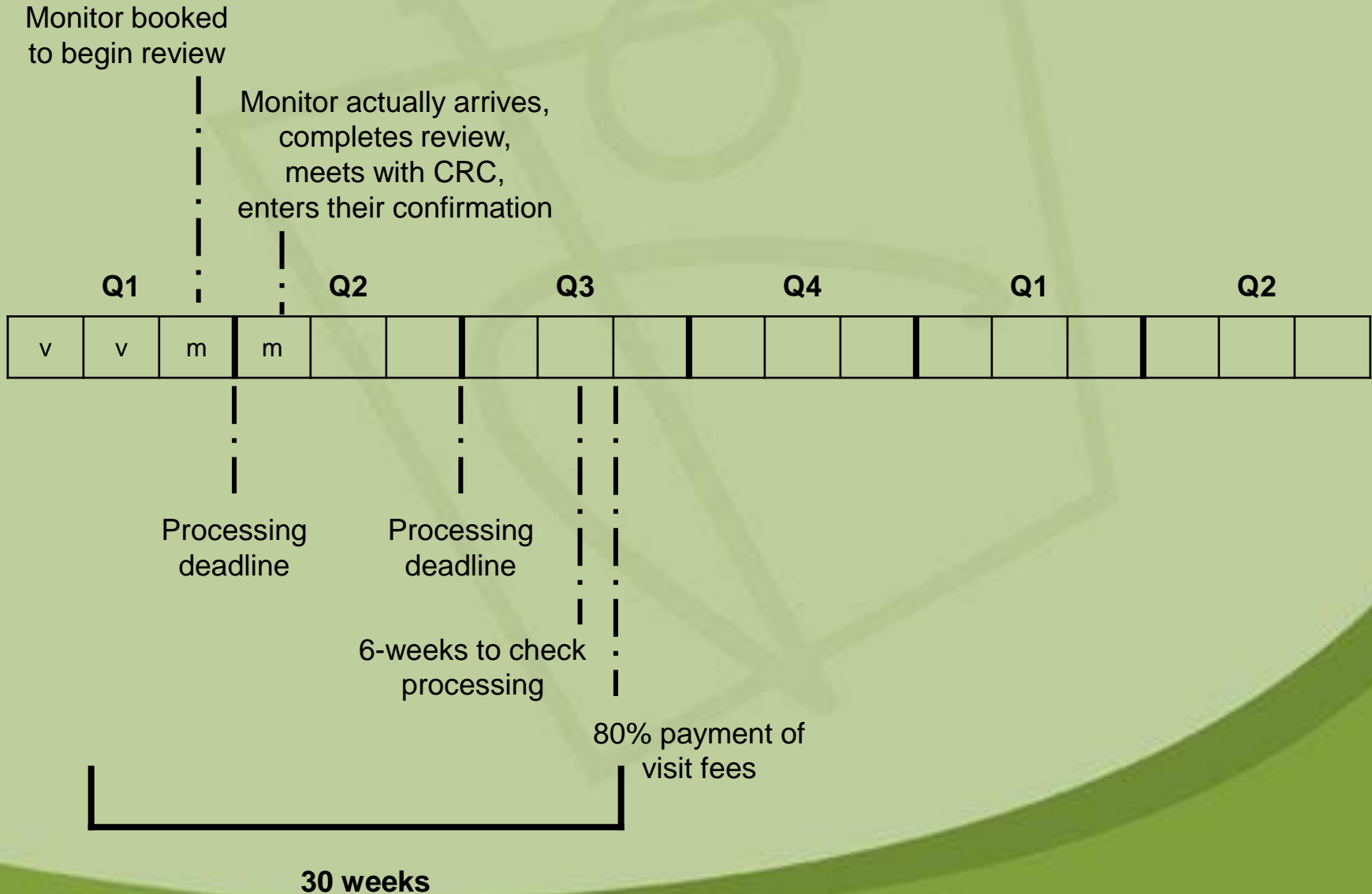
1. Decline in good Canadian studies



2. Missing national BD support

- The US-based Sponsors Urban Myths about Canada:
 - Slow review process
 - Tough requirements
 - Painful labelling requirements
 - etc...
- Reality:
 - NDA = HC Application +
Certificate of Analysis (CoA)
 - (if available: validation of analytical procedures and manufacturing process)

3. Current Payment Systems



3. Current Payment Systems

- Planning
 - Line of credit
 - Rightsizing
 - Balance of short-term vs long-term contracts
 - Approach to negotiation

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