Check-Cap Files CE Mark Registration for C-Scan®

September 27, 2017

Safe Harbor statement

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Highlights

C-Scan Overview

- Ingestible capsule system for preparation-free colorectal cancer (CRC) screening, submitted for CE Mark approval
- Patient friendly: short and autonomous procedure, no change in patient diet and lifestyle

Clinical study, major outcomes

- Positive safety profile
  - Capsule well tolerated, no C-Scan related serious adverse events
  - Ultra-low radiation dose of 0.05 mSv (average)

Highlights

Clinical study, major outcomes (continued)

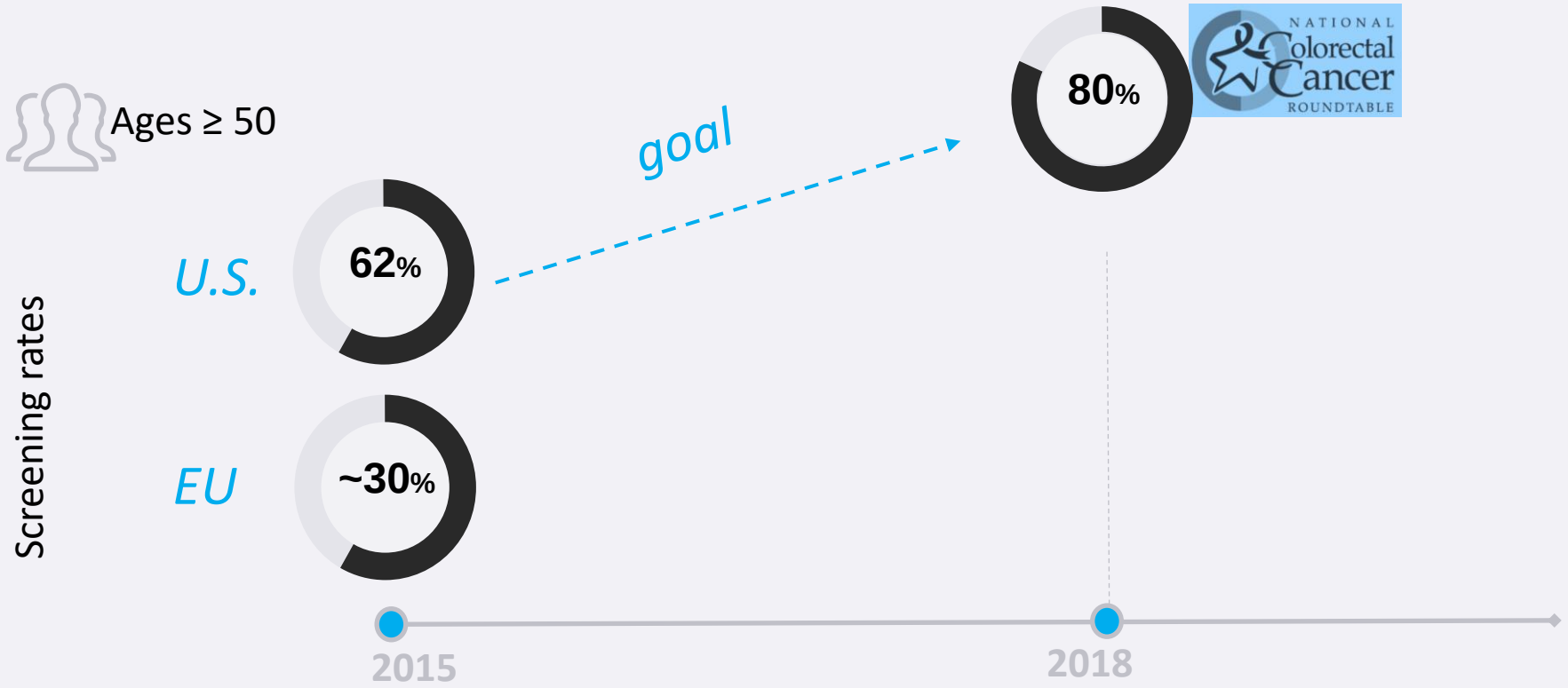
- Performance: clinical feasibility and clinical utility[(1)]
  - 44% sensitivity, 89% specificity for detection of patients with polyps (n=45)
  - Strong correlation between scanning coverage and polyp detection (R-squared=0.98)
    - 78% sensitivity, 90% specificity when >50% of the colon was scanned (p=<0.05)
    - 100% sensitivity, 86% specificity with over 70% of the colon scanned (p=<0.05)

CE Mark registration paves way for EU and US markets

- Continue clinical & system optimization program to achieve consistently high colon scanning coverage
  - Advanced C-Scan version underway in clinical evaluation
- H118: EU post-market study initiation
- H118: US Pilot study initiation
- Evaluate marketing and commercialization paths throughout 2018

[(1)] In Europe, stool testing is the primary CRC screening test; sensitivity for advanced adenomas ranges from 22% to 40%

Screening in the U.S. and EU
a substantially underused strategy



Sources: CDC NHIS survey results as published in the CDC's MMWR between 2006 and 2017
Radiology,. 2017, Ahead of Print, https://doi.org/10.1148/radiol.2017170924 (Smith)

CE Mark Clinical Performance
Study parameters

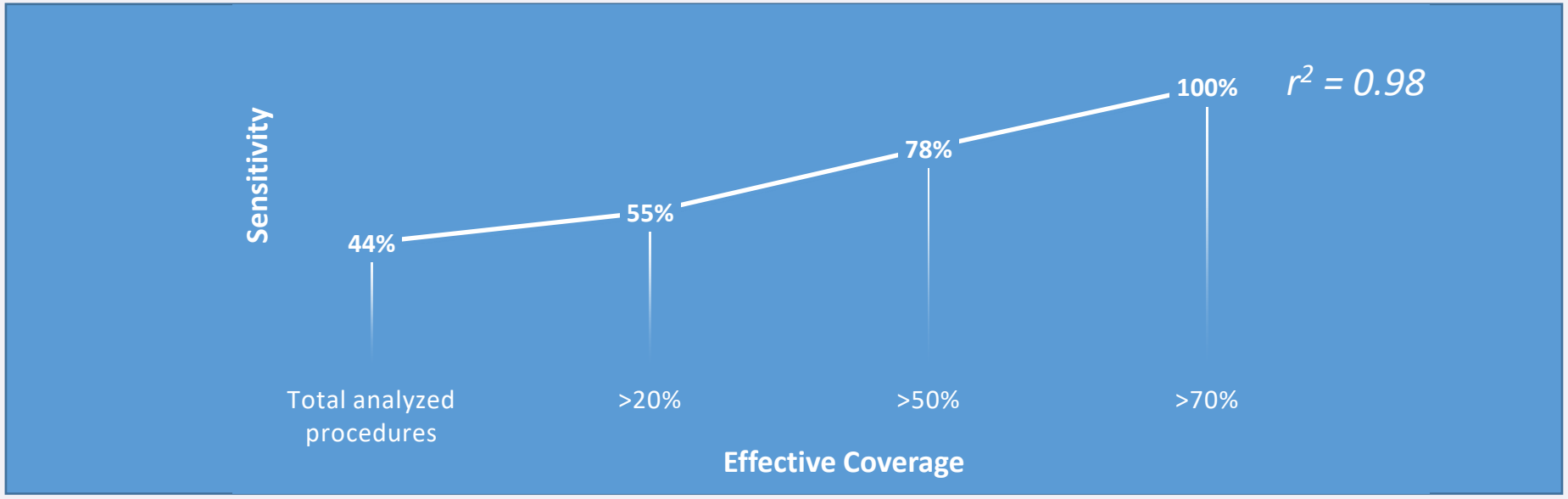
Device technology	✓ C-Scan system (current version)
Objectives	✓ Safety ✓ Clinical performance of preparation-free C-Scan system detection of patients with polyps
Subjects	66 patients enrolled ✓ 43 with un-resected polyps ✓ 23 average-risk
Site locations	Israel (3 sites)
Procedures	✓ 63 patients completed the C-Scan procedure ✓ 45 patients included in analysis for polyps ✓ All received stool testing and confirmatory colonoscopy
Case review	Colonoscopy performed by independent investigator Central reviewers (including 1 independent MD) reviewed all C-Scan cases (blinded to colonoscopy results) Colonoscopy and C-Scan results adjudicated by independent MD

CE Mark Clinical Performance Study
Safety

- 52 ± 32 hours average transit time with no change in routine or diet
- 0.05 mSv average radiation dosage
  - abdominal CT scan dose exposure is ~6.0 mSv
- No device related serious adverse events
- Minor anticipated adverse events
  - Soft stool, abdominal cramps, headache
  - 1 case of skin irritation (under the track)
  - All resolved in a short period of time and without any medical intervention

CE Mark Clinical Performance Study
C-Scan clinical performance

Effective coverage	Sensitivity	Specificity	Subjects
All analyzed procedures	44%	89%	45
>20%	55%	89%	35
>50%	78% (p<0.05)	90%	19
>70%	100% (p<0.05)	86%	12

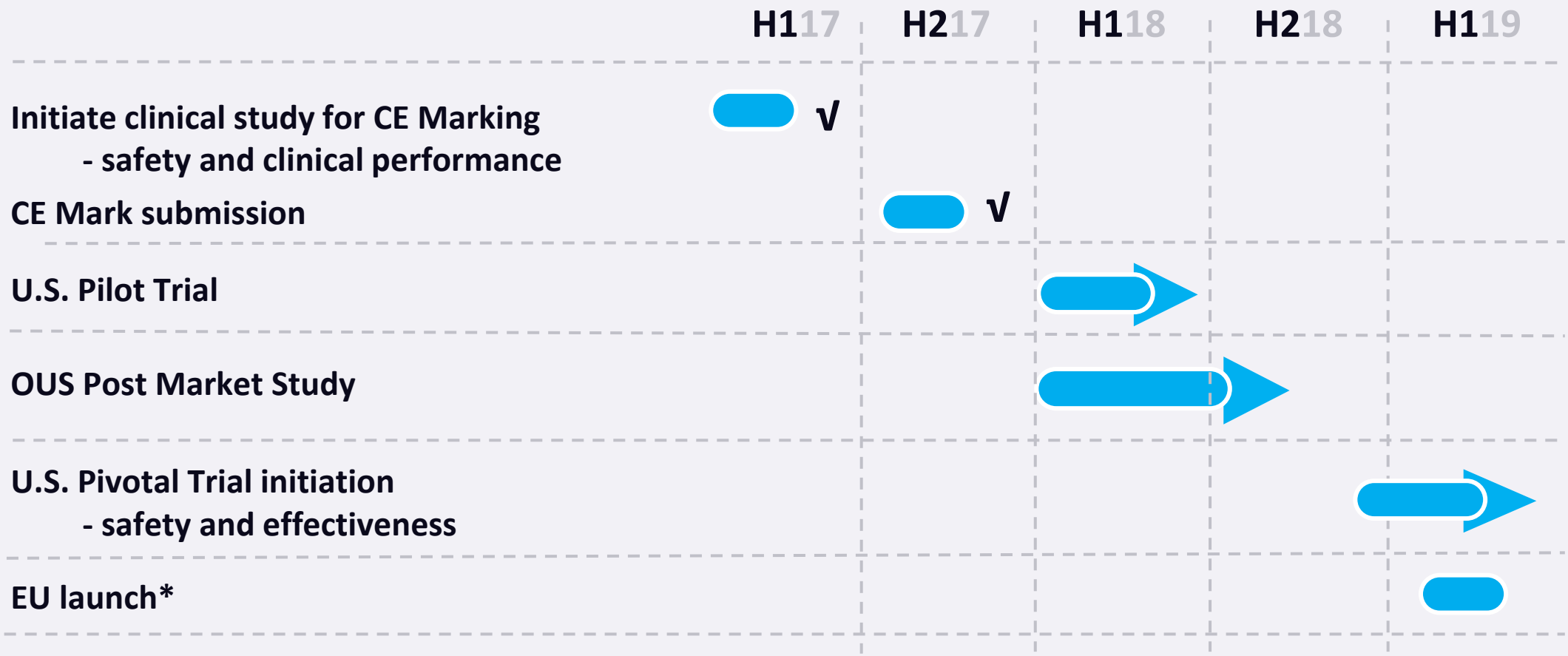


New C-Scan Version
Short-term development objectives

Enhanced performance through:

- Consistent colon scan coverage
  - More efficient power management
  - Scan Control Algorithm optimization
  - Improved tracking accuracy
  - Implementation (mostly software) and clinical testing underway
- Improved system manufacturing processes

Development
milestones



* Capital and strategic partner dependent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