



**How the IDEIA findings are being interpreted in daily**

**Clinical Practice**



# Study Overview

Stage III  
Colon  
Cancer  
Patients



12,834 patients

3 months

FOLFOX\*  
or CAPOX\*

6 months

\*Investigator's choice, no  
randomization

- **Objective:**

Reduce side-effects of therapy  
without giving up (too much) anti-  
cancer efficacy of therapy

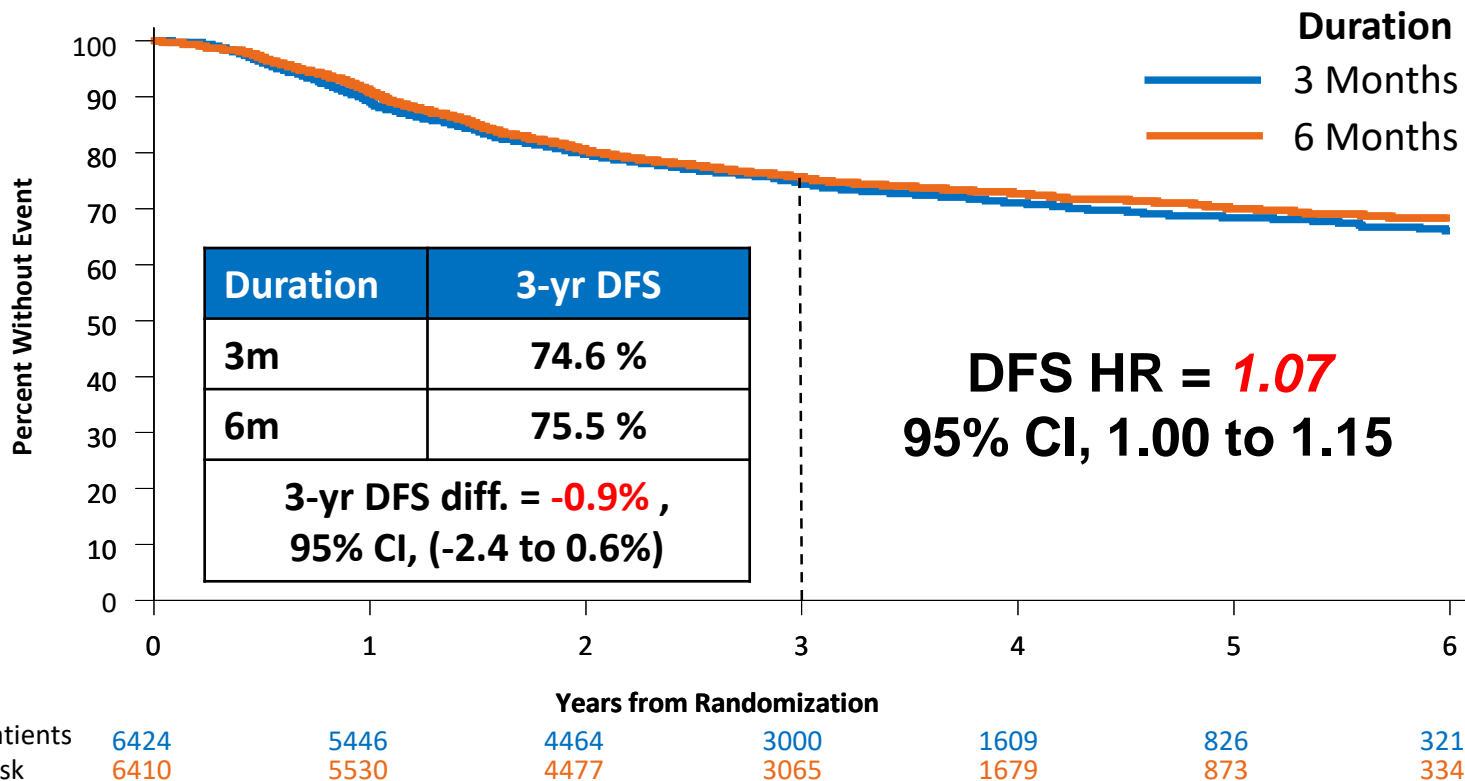
- **Non-inferiority design:**

As agreed upon by patient advocates  
and oncologists, shorter duration of  
therapy should not sacrifice more than  
12% of benefit of adjuvant therapy

**In statistical terms: upper 95%  
confidence interval of Hazard Ratio (HR)  
of disease free survival (DFS) should not  
exceed 1.12**

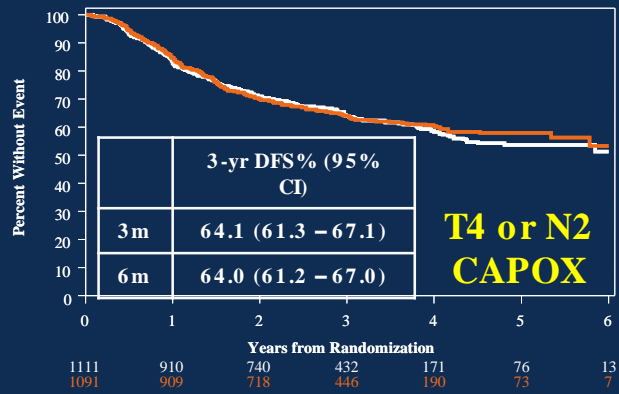
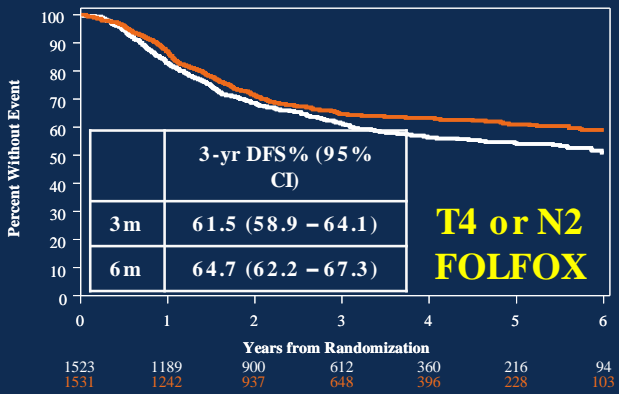
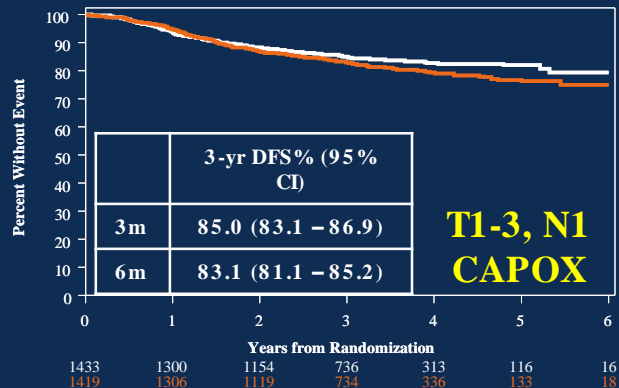
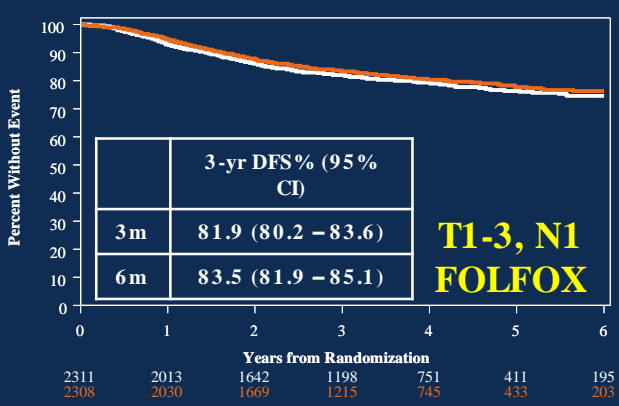


# Primary Outcomes Analysis





# DFS Comparison by Risk Group and Regimen, cont.



Duration  
 — 3 Months  
 — 6 Months



**3 yr DFS rate (%)  
and HR by  
regimen and  
risk group**

|               |  | Regimen              |     |                |                      |     |                |                      |     |                       |
|---------------|--|----------------------|-----|----------------|----------------------|-----|----------------|----------------------|-----|-----------------------|
|               |  | CAPOX                |     |                | FOLFOX               |     |                |                      |     | CAPOX/FOLFOX combined |
|               |  | 3 yr DFS, % (95% CI) |     | HR<br>(95% CI) | 3 yr DFS, % (95% CI) |     | HR<br>(95% CI) | 3 yr DFS, % (95% CI) |     | HR<br>(95% CI)        |
|               |  | 3 m                  | 6 m |                | 3 m                  | 6 m |                | 3 m                  | 6 m |                       |
| Risk<br>group | Low-risk<br>(T1-3 N1)<br>~60%            |                      |     |                |                      |     |                |                      |     |                       |
|               | High-risk<br>(T4 and /<br>or N2)<br>~40% |                      |     |                |                      |     |                |                      |     |                       |
|               | Risk<br>groups<br>combined               |                      |     |                |                      |     |                |                      |     |                       |

Non-inferior

Not proven

Inferior



**3 yr DFS rate (%) and HR by regimen and risk group**

|            |                                 | Regimen                    |                            |                            |                      |     |                | CAPOX/FOLFOX combined |     |                |
|------------|---------------------------------|----------------------------|----------------------------|----------------------------|----------------------|-----|----------------|-----------------------|-----|----------------|
|            |                                 | CAPOX                      |                            |                            | FOLFOX               |     |                |                       |     |                |
|            |                                 | 3 yr DFS, % (95% CI)       |                            | HR<br>(95% CI)             | 3 yr DFS, % (95% CI) |     | HR<br>(95% CI) | 3 yr DFS, % (95% CI)  |     | HR<br>(95% CI) |
|            |                                 | 3 m                        | 6 m                        |                            | 3 m                  | 6 m |                | 3 m                   | 6 m |                |
| Risk group | Low-risk (T1-3 N1) ~60%         | <b>85.0</b><br>(83.1-86.9) | <b>83.1</b><br>(81.1-85.2) | <b>0.85</b><br>(0.71-1.01) |                      |     |                |                       |     |                |
|            | High-risk (T4 and / or N2) ~40% |                            |                            |                            |                      |     |                |                       |     |                |
|            | Risk groups combined            |                            |                            |                            |                      |     |                |                       |     |                |

Non-inferior

Not proven

Inferior



**3 yr DFS rate (%) and HR by regimen and risk group**

|            |                                 | Regimen                    |                            |                            |                            |                            |                            |                      |     |                       |
|------------|---------------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------|-----|-----------------------|
|            |                                 | CAPOX                      |                            |                            | FOLFOX                     |                            |                            |                      |     | CAPOX/FOLFOX combined |
|            |                                 | 3 yr DFS, % (95% CI)       |                            | HR<br>(95% CI)             | 3 yr DFS, % (95% CI)       |                            | HR<br>(95% CI)             | 3 yr DFS, % (95% CI) |     | HR<br>(95% CI)        |
|            |                                 | 3 m                        | 6 m                        |                            | 3 m                        | 6 m                        |                            | 3 m                  | 6 m |                       |
| Risk group | Low-risk (T1-3 N1) ~60%         | <b>85.0</b><br>(83.1-86.9) | <b>83.1</b><br>(81.1-85.2) | <b>0.85</b><br>(0.71-1.01) |                            |                            |                            |                      |     |                       |
|            | High-risk (T4 and / or N2) ~40% |                            |                            |                            | <b>61.5</b><br>(58.9-64.1) | <b>64.7</b><br>(62.2-67.3) | <b>1.20</b><br>(1.07-1.35) |                      |     |                       |
|            | Risk groups combined            |                            |                            |                            |                            |                            |                            |                      |     |                       |

**Non-inferior**

**Not proven**

**Inferior**



**3 yr DFS rate (%) and HR by regimen and risk group**

|            |                                 | Regimen                    |                            |                            |                            |                            |                            |                            |                            |                            |
|------------|---------------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
|            |                                 | CAPOX                      |                            |                            | FOLFOX                     |                            |                            | CAPOX/FOLFOX combined      |                            |                            |
|            |                                 | 3 yr DFS, % (95% CI)       |                            | HR<br>(95% CI)             | 3 yr DFS, % (95% CI)       |                            | HR<br>(95% CI)             | 3 yr DFS, % (95% CI)       |                            | HR<br>(95% CI)             |
|            |                                 | 3 m                        | 6 m                        |                            | 3 m                        | 6 m                        |                            | 3 m                        | 6 m                        |                            |
| Risk group | Low-risk (T1-3 N1) ~60%         | <b>85.0</b><br>(83.1-86.9) | <b>83.1</b><br>(81.1-85.2) | <b>0.85</b><br>(0.71-1.01) |                            |                            |                            |                            |                            |                            |
|            | High-risk (T4 and / or N2) ~40% | <b>64.1</b><br>(61.3-67.1) | <b>64.0</b><br>(61.2-67.0) | <b>1.02</b><br>(0.89-1.17) | <b>61.5</b><br>(58.9-64.1) | <b>64.7</b><br>(62.2-67.3) | <b>1.20</b><br>(1.07-1.35) | <b>62.7</b><br>(60.8-64.4) | <b>64.4</b><br>(62.6-66.4) | <b>1.12</b><br>(1.03-1.23) |
|            | Risk groups combined            | <b>75.9</b><br>(74.2-77.6) | <b>74.8</b><br>(73.1-76.6) | <b>0.95</b><br>(0.85-1.06) |                            |                            |                            |                            |                            |                            |

**Non-inferior**

**Not proven**

**Inferior**





**3 yr DFS rate (%) and HR by regimen and risk group**

|            |                                 | Regimen                    |                            |                            |                            |                            |                            |                            |                            |                            |
|------------|---------------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
|            |                                 | CAPOX                      |                            |                            | FOLFOX                     |                            |                            |                            |                            | CAPOX/FOLFOX combined      |
|            |                                 | 3 yr DFS, % (95% CI)       |                            | HR<br>(95% CI)             | 3 yr DFS, % (95% CI)       |                            | HR<br>(95% CI)             | 3 yr DFS, % (95% CI)       |                            | HR<br>(95% CI)             |
|            |                                 | 3 m                        | 6 m                        |                            | 3 m                        | 6 m                        |                            | 3 m                        | 6 m                        |                            |
| Risk group | Low-risk (T1-3 N1) ~60%         | <b>85.0</b><br>(83.1-86.9) | <b>83.1</b><br>(81.1-85.2) | <b>0.85</b><br>(0.71-1.01) | <b>81.9</b><br>(80.2-83.6) | <b>83.5</b><br>(81.9-85.1) | <b>1.10</b><br>(0.96-1.26) | <b>83.1</b><br>(81.8-84.4) | <b>83.3</b><br>(82.1-84.6) | <b>1.01</b><br>(0.90-1.12) |
|            | High-risk (T4 and / or N2) ~40% | <b>64.1</b><br>(61.3-67.1) | <b>64.0</b><br>(61.2-67.0) | <b>1.02</b><br>(0.89-1.17) | <b>61.5</b><br>(58.9-64.1) | <b>64.7</b><br>(62.2-67.3) | <b>1.20</b><br>(1.07-1.35) | <b>62.7</b><br>(60.8-64.4) | <b>64.4</b><br>(62.6-66.4) | <b>1.12</b><br>(1.03-1.23) |
|            | Risk groups combined            | <b>75.9</b><br>(74.2-77.6) | <b>74.8</b><br>(73.1-76.6) | <b>0.95</b><br>(0.85-1.06) | <b>73.6</b><br>(72.2-75.1) | <b>76.0</b><br>(74.6-77.5) | <b>1.16</b><br>(1.06-1.26) |                            |                            |                            |

**Non-inferior**

**Not proven**

**Inferior**



**3 yr DFS rate (%) and HR by regimen and risk group**

|            |                                 | Regimen                    |                            |                            |                            |                            |                            |   |                            |                            |
|------------|---------------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|---|----------------------------|----------------------------|
|            |                                 | CAPOX                      |                            |                            | FOLFOX                     |                            |                            | CAPOX/FOLFOX combined   |                            |                            |
|            |                                 | 3 yr DFS, % (95% CI)       |                            | HR<br>(95% CI)             | 3 yr DFS, % (95% CI)       |                            | HR<br>(95% CI)             | 3 yr DFS, % (95% CI)  |                            | HR<br>(95% CI)             |
|            |                                 | 3 m                        | 6 m                        |                            | 3 m                        | 6 m                        |                            | 3 m   | 6 m                        |                            |
| Risk group | Low-risk (T1-3 N1) ~60%         | <b>85.0</b><br>(83.1-86.9) | <b>83.1</b><br>(81.1-85.2) | <b>0.85</b><br>(0.71-1.01) | <b>81.9</b><br>(80.2-83.6) | <b>83.5</b><br>(81.9-85.1) | <b>1.10</b><br>(0.96-1.26) | <b>83.1</b><br>(81.8-84.4)  | <b>83.3</b><br>(82.1-84.6) | <b>1.01</b><br>(0.90-1.12) |
|            | High-risk (T4 and / or N2) ~40% | <b>64.1</b><br>(61.3-67.1) | <b>64.0</b><br>(61.2-67.0) | <b>1.02</b><br>(0.89-1.17) | <b>61.5</b><br>(58.9-64.1) | <b>64.7</b><br>(62.2-67.3) | <b>1.20</b><br>(1.07-1.35) | <b>62.7</b><br>(60.8-64.4)  | <b>64.4</b><br>(62.6-66.4) | <b>1.12</b><br>(1.03-1.23) |
|            | Risk groups combined            | <b>75.9</b><br>(74.2-77.6) | <b>74.8</b><br>(73.1-76.6) | <b>0.95</b><br>(0.85-1.06) | <b>73.6</b><br>(72.2-75.1) | <b>76.0</b><br>(74.6-77.5) | <b>1.16</b><br>(1.06-1.26) | <b>P-value interaction test:</b><br><b>Regimen: 0.0061</b><br><b>Risk group: 0.11</b> |                            |                            |

**Non-inferior**

**Not proven**

**Inferior**



# Proposal

- **Prospective registry of adjuvant schedule in stage III Colon Cancer**
  - Age,
  - Gender,
  - T
  - No Positive Lymph Nodes
  - No of Retrieved Lymph Nodes
  - N1c
  - Regimen (FOLFOX vs. CAPOX)
  - 3 vs. 6 months
- **1/2019-12/2021**
  - Before June 2020
  - After June 2020



# E-Database from GIS-CG



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| <a href="#">NEARCHOS</a>                                  | 11      | 408      | 11 forms   |                          |        |  |
| <a href="#">EMKAPES COLORECTAL CANCER REGISTRY</a>        | 377     | 485      | 13 forms   |                          |        |  |
| <a href="#">EMKAPES COLORECTAL CANCER CASES 2015-2016</a> | 105     | 484      | 13 forms   |                          |        |  |
| <a href="#">EMKAPES PANCREATIC CANCER REGISTRY</a>        | 1       | 430      | 11 forms   |                          |        |  |