Datastat Research
Building Capacity in Training and Research

# DATASTAT TRAINING IN

OFFICIAL COURSE PROSPECTUS

Center for Advanced Research & Professional Development

Nairobi Training Center • Global Virtual Academy • Corporate On-Site

BIOTECHNOLOGY AND PHARMACEUTICAL DEVELOPMENT

# Regulatory Strategy for Companion Diagnostics Training Course

Comprehensive Course Syllabus, Practical Modules & Upcoming Schedules

## PROGRAM SPECIFICATIONS & HIGHLIGHTS

DURATION
**10 Days Practical Hands-on**

DELIVERY MODES
**In-Person Class & Live Virtual**

CERTIFICATION
**Accredited Certificate of Completion**

INTAKES / DATES
**Multiple Cohort Schedules Included**

PREPARED FOR:

**Valued Participant**

Email: training@datastatresearch.org | Issued: November 25, 2026

**Academic & Professional Training Year: 2026**

**DATASTAT TRAINING INSTITUTE**

P.O. Box 102802-00101, Nairobi, Kenya

Training Centers: Nairobi • Mombasa • Kigali • Dubai • Live Virtual Academy

Tel: +254 724 527 104 | +254 734 969 612

Email: training@datastatresearch.org

**www.datastatresearch.org**

# Regulatory Strategy for Companion Diagnostics Training Course

**Biotechnology and Pharmaceutical Development • 10 Days Intensive • Accredited Certification**

## Course Overview

Regulatory Strategy for Companion Diagnostics Training Course is designed to equip professionals with the knowledge and strategic acumen needed to navigate this complex landscape, from initial biomarker discovery and co-development to market access and post-market surveillance.

### Key Skills & Software Tools Covered

Regulatory submissions • diagnostics development • strategy planning

## Upcoming Training Schedules

Confirmed cohort intakes and venues. Both physical in-person classroom and live virtual online seats are available.

| TRAINING DATES | LOCATION / VENUE | FORMAT / DURATION | INVESTMENT (FEE) |
|---|---|---|---|
| **30 Nov 2026 – 11 Dec 2026** | Nairobi | Classroom / 10d | **$4,000 USD / KES 250,000** |
| **30 Nov 2026 – 11 Dec 2026** | Kigali | Classroom / 10d | **$6,000 USD / KES 110,000** |
| **30 Nov 2026 – 11 Dec 2026** | Dubai | Classroom / 10d | **$10,000 USD / KES 110,000** |
| **30 Nov 2026 – 11 Dec 2026** | Cape Town | Classroom / 10d | **$9,000 USD / KES 110,000** |
| **30 Nov 2026 – 11 Dec 2026** | Addis Ababa | Classroom / 10d | **$6,000 USD / KES 110,000** |
| **30 Nov 2026 – 11 Dec 2026** | Singapore | Classroom / 10d | **$10,000 USD / KES 110,000** |
| **30 Nov 2026 – 11 Dec 2026** | Istanbul | Classroom / 10d | **$10,000 USD / KES 110,000** |
| **30 Nov 2026 – 11 Dec 2026** | Bangkok | Classroom / 10d | **$10,000 USD / KES 110,000** |
| **30 Nov 2026 – 11 Dec 2026** | Accra | Classroom / 10d | **$8,000 USD / KES 110,000** |
| **14 Dec 2026 – 25 Dec 2026** | Nairobi | Classroom / 10d | **$4,000 USD / KES 250,000** |
| **14 Dec 2026 – 25 Dec 2026** | Kigali | Classroom / 10d | **$6,000 USD / KES 110,000** |
| **14 Dec 2026 – 25 Dec 2026** | Dubai | Classroom / 10d | **$10,000 USD / KES 110,000** |
| **14 Dec 2026 – 25 Dec 2026** | Cape Town | Classroom / 10d | **$9,000 USD / KES 110,000** |
| **14 Dec 2026 – 25 Dec 2026** | Addis Ababa | Classroom / 10d | **$6,000 USD / KES 110,000** |
| **14 Dec 2026 – 25 Dec 2026** | Singapore | Classroom / 10d | **$10,000 USD / KES 110,000** |
| **14 Dec 2026 – 25 Dec 2026** | Istanbul | Classroom / 10d | **$10,000 USD / KES 110,000** |
| **14 Dec 2026 – 25 Dec 2026** | Bangkok | Classroom / 10d | **$10,000 USD / KES 110,000** |
| **14 Dec 2026 – 25 Dec 2026** | Accra | Classroom / 10d | **$8,000 USD / KES 110,000** |
| **4 Jan 2027 – 15 Jan 2027** | Nairobi | Classroom / 10d | **$3,000 USD / KES 220,000** |
| **4 Jan 2027 – 15 Jan 2027** | Kigali | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **4 Jan 2027 – 15 Jan 2027** | Dubai | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **4 Jan 2027 – 15 Jan 2027** | Cape Town | Classroom / 10d | **$9,000 USD / KES 220,000** |
| **4 Jan 2027 – 15 Jan 2027** | Addis Ababa | Classroom / 10d | **$6,000 USD / KES 220,000** |

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| **4 Jan 2027 – 15 Jan 2027** | Singapore | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **4 Jan 2027 – 15 Jan 2027** | Istanbul | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **4 Jan 2027 – 15 Jan 2027** | Bangkok | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **4 Jan 2027 – 15 Jan 2027** | Accra | Classroom / 10d | **$8,000 USD / KES 220,000** |
| **18 Jan 2027 – 29 Jan 2027** | Nairobi | Classroom / 10d | **$3,000 USD / KES 220,000** |
| **18 Jan 2027 – 29 Jan 2027** | Kigali | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **18 Jan 2027 – 29 Jan 2027** | Dubai | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **18 Jan 2027 – 29 Jan 2027** | Cape Town | Classroom / 10d | **$9,000 USD / KES 220,000** |
| **18 Jan 2027 – 29 Jan 2027** | Addis Ababa | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **18 Jan 2027 – 29 Jan 2027** | Singapore | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **18 Jan 2027 – 29 Jan 2027** | Istanbul | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **18 Jan 2027 – 29 Jan 2027** | Bangkok | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **18 Jan 2027 – 29 Jan 2027** | Accra | Classroom / 10d | **$8,000 USD / KES 220,000** |
| **1 Feb 2027 – 12 Feb 2027** | Nairobi | Classroom / 10d | **$3,000 USD / KES 220,000** |
| **1 Feb 2027 – 12 Feb 2027** | Kigali | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **1 Feb 2027 – 12 Feb 2027** | Dubai | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **1 Feb 2027 – 12 Feb 2027** | Cape Town | Classroom / 10d | **$9,000 USD / KES 220,000** |
| **1 Feb 2027 – 12 Feb 2027** | Addis Ababa | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **1 Feb 2027 – 12 Feb 2027** | Singapore | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **1 Feb 2027 – 12 Feb 2027** | Istanbul | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **1 Feb 2027 – 12 Feb 2027** | Bangkok | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **1 Feb 2027 – 12 Feb 2027** | Accra | Classroom / 10d | **$8,000 USD / KES 220,000** |
| **15 Feb 2027 – 26 Feb 2027** | Nairobi | Classroom / 10d | **$3,000 USD / KES 220,000** |
| **15 Feb 2027 – 26 Feb 2027** | Kigali | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **15 Feb 2027 – 26 Feb 2027** | Dubai | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **15 Feb 2027 – 26 Feb 2027** | Cape Town | Classroom / 10d | **$9,000 USD / KES 220,000** |
| **15 Feb 2027 – 26 Feb 2027** | Addis Ababa | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **15 Feb 2027 – 26 Feb 2027** | Singapore | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **15 Feb 2027 – 26 Feb 2027** | Istanbul | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **15 Feb 2027 – 26 Feb 2027** | Bangkok | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **15 Feb 2027 – 26 Feb 2027** | Accra | Classroom / 10d | **$8,000 USD / KES 220,000** |
| **1 Mar 2027 – 12 Mar 2027** | Nairobi | Classroom / 10d | **$3,000 USD / KES 220,000** |

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|---|---|---|---|
| **1 Mar 2027 – 12 Mar 2027** | Kigali | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **1 Mar 2027 – 12 Mar 2027** | Dubai | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **1 Mar 2027 – 12 Mar 2027** | Cape Town | Classroom / 10d | **$9,000 USD / KES 220,000** |
| **1 Mar 2027 – 12 Mar 2027** | Addis Ababa | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **1 Mar 2027 – 12 Mar 2027** | Singapore | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **1 Mar 2027 – 12 Mar 2027** | Istanbul | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **1 Mar 2027 – 12 Mar 2027** | Bangkok | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **1 Mar 2027 – 12 Mar 2027** | Accra | Classroom / 10d | **$8,000 USD / KES 220,000** |
| **15 Mar 2027 – 26 Mar 2027** | Nairobi | Classroom / 10d | **$3,000 USD / KES 220,000** |
| **15 Mar 2027 – 26 Mar 2027** | Kigali | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **15 Mar 2027 – 26 Mar 2027** | Dubai | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **15 Mar 2027 – 26 Mar 2027** | Cape Town | Classroom / 10d | **$9,000 USD / KES 220,000** |
| **15 Mar 2027 – 26 Mar 2027** | Addis Ababa | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **15 Mar 2027 – 26 Mar 2027** | Singapore | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **15 Mar 2027 – 26 Mar 2027** | Istanbul | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **15 Mar 2027 – 26 Mar 2027** | Bangkok | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **15 Mar 2027 – 26 Mar 2027** | Accra | Classroom / 10d | **$8,000 USD / KES 220,000** |
| **29 Mar 2027 – 9 Apr 2027** | Nairobi | Classroom / 10d | **$3,000 USD / KES 220,000** |
| **29 Mar 2027 – 9 Apr 2027** | Kigali | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **29 Mar 2027 – 9 Apr 2027** | Dubai | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **29 Mar 2027 – 9 Apr 2027** | Cape Town | Classroom / 10d | **$9,000 USD / KES 220,000** |
| **29 Mar 2027 – 9 Apr 2027** | Addis Ababa | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **29 Mar 2027 – 9 Apr 2027** | Singapore | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **29 Mar 2027 – 9 Apr 2027** | Istanbul | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **29 Mar 2027 – 9 Apr 2027** | Bangkok | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **29 Mar 2027 – 9 Apr 2027** | Accra | Classroom / 10d | **$8,000 USD / KES 220,000** |
| **12 Apr 2027 – 23 Apr 2027** | Nairobi | Classroom / 10d | **$3,000 USD / KES 220,000** |
| **12 Apr 2027 – 23 Apr 2027** | Kigali | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **12 Apr 2027 – 23 Apr 2027** | Dubai | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **12 Apr 2027 – 23 Apr 2027** | Cape Town | Classroom / 10d | **$9,000 USD / KES 220,000** |
| **12 Apr 2027 – 23 Apr 2027** | Addis Ababa | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **12 Apr 2027 – 23 Apr 2027** | Singapore | Classroom / 10d | **$10,000 USD / KES 220,000** |

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| **12 Apr 2027 – 23 Apr 2027** | Istanbul | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **12 Apr 2027 – 23 Apr 2027** | Bangkok | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **12 Apr 2027 – 23 Apr 2027** | Accra | Classroom / 10d | **$8,000 USD / KES 220,000** |
| **26 Apr 2027 – 7 May 2027** | Nairobi | Classroom / 10d | **$3,000 USD / KES 220,000** |
| **26 Apr 2027 – 7 May 2027** | Kigali | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **26 Apr 2027 – 7 May 2027** | Dubai | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **26 Apr 2027 – 7 May 2027** | Cape Town | Classroom / 10d | **$9,000 USD / KES 220,000** |
| **26 Apr 2027 – 7 May 2027** | Addis Ababa | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **26 Apr 2027 – 7 May 2027** | Singapore | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **26 Apr 2027 – 7 May 2027** | Istanbul | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **26 Apr 2027 – 7 May 2027** | Bangkok | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **26 Apr 2027 – 7 May 2027** | Accra | Classroom / 10d | **$8,000 USD / KES 220,000** |
| **10 May 2027 – 21 May 2027** | Nairobi | Classroom / 10d | **$3,000 USD / KES 220,000** |
| **10 May 2027 – 21 May 2027** | Kigali | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **10 May 2027 – 21 May 2027** | Dubai | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **10 May 2027 – 21 May 2027** | Cape Town | Classroom / 10d | **$9,000 USD / KES 220,000** |
| **10 May 2027 – 21 May 2027** | Addis Ababa | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **10 May 2027 – 21 May 2027** | Singapore | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **10 May 2027 – 21 May 2027** | Istanbul | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **10 May 2027 – 21 May 2027** | Bangkok | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **10 May 2027 – 21 May 2027** | Accra | Classroom / 10d | **$8,000 USD / KES 220,000** |
| **24 May 2027 – 4 Jun 2027** | Nairobi | Classroom / 10d | **$3,000 USD / KES 220,000** |
| **24 May 2027 – 4 Jun 2027** | Kigali | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **24 May 2027 – 4 Jun 2027** | Dubai | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **24 May 2027 – 4 Jun 2027** | Cape Town | Classroom / 10d | **$9,000 USD / KES 220,000** |
| **24 May 2027 – 4 Jun 2027** | Addis Ababa | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **24 May 2027 – 4 Jun 2027** | Singapore | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **24 May 2027 – 4 Jun 2027** | Istanbul | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **24 May 2027 – 4 Jun 2027** | Bangkok | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **24 May 2027 – 4 Jun 2027** | Accra | Classroom / 10d | **$8,000 USD / KES 220,000** |
| **7 Jun 2027 – 18 Jun 2027** | Addis Ababa | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **7 Jun 2027 – 18 Jun 2027** | Singapore | Classroom / 10d | **$10,000 USD / KES 220,000** |

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| **7 Jun 2027 – 18 Jun 2027** | Istanbul | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **7 Jun 2027 – 18 Jun 2027** | Bangkok | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **7 Jun 2027 – 18 Jun 2027** | Accra | Classroom / 10d | **$8,000 USD / KES 220,000** |
| **7 Jun 2027 – 18 Jun 2027** | Nairobi | Classroom / 10d | **$3,000 USD / KES 220,000** |
| **7 Jun 2027 – 18 Jun 2027** | Kigali | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **7 Jun 2027 – 18 Jun 2027** | Dubai | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **7 Jun 2027 – 18 Jun 2027** | Cape Town | Classroom / 10d | **$9,000 USD / KES 220,000** |
| **21 Jun 2027 – 2 Jul 2027** | Nairobi | Classroom / 10d | **$3,000 USD / KES 220,000** |
| **21 Jun 2027 – 2 Jul 2027** | Kigali | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **21 Jun 2027 – 2 Jul 2027** | Dubai | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **21 Jun 2027 – 2 Jul 2027** | Cape Town | Classroom / 10d | **$9,000 USD / KES 220,000** |
| **21 Jun 2027 – 2 Jul 2027** | Addis Ababa | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **21 Jun 2027 – 2 Jul 2027** | Singapore | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **21 Jun 2027 – 2 Jul 2027** | Istanbul | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **21 Jun 2027 – 2 Jul 2027** | Bangkok | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **21 Jun 2027 – 2 Jul 2027** | Accra | Classroom / 10d | **$8,000 USD / KES 220,000** |
| **5 Jul 2027 – 16 Jul 2027** | Nairobi | Classroom / 10d | **$3,000 USD / KES 220,000** |
| **5 Jul 2027 – 16 Jul 2027** | Kigali | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **5 Jul 2027 – 16 Jul 2027** | Dubai | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **5 Jul 2027 – 16 Jul 2027** | Cape Town | Classroom / 10d | **$9,000 USD / KES 220,000** |
| **5 Jul 2027 – 16 Jul 2027** | Addis Ababa | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **5 Jul 2027 – 16 Jul 2027** | Singapore | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **5 Jul 2027 – 16 Jul 2027** | Istanbul | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **5 Jul 2027 – 16 Jul 2027** | Bangkok | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **5 Jul 2027 – 16 Jul 2027** | Accra | Classroom / 10d | **$8,000 USD / KES 220,000** |
| **19 Jul 2027 – 30 Jul 2027** | Nairobi | Classroom / 10d | **$3,000 USD / KES 220,000** |
| **19 Jul 2027 – 30 Jul 2027** | Kigali | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **19 Jul 2027 – 30 Jul 2027** | Dubai | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **19 Jul 2027 – 30 Jul 2027** | Cape Town | Classroom / 10d | **$9,000 USD / KES 220,000** |
| **19 Jul 2027 – 30 Jul 2027** | Addis Ababa | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **19 Jul 2027 – 30 Jul 2027** | Singapore | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **19 Jul 2027 – 30 Jul 2027** | Istanbul | Classroom / 10d | **$10,000 USD / KES 220,000** |

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| **19 Jul 2027 – 30 Jul 2027** | Bangkok | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **19 Jul 2027 – 30 Jul 2027** | Accra | Classroom / 10d | **$8,000 USD / KES 220,000** |
| **2 Aug 2027 – 13 Aug 2027** | Nairobi | Classroom / 10d | **$3,000 USD / KES 220,000** |
| **2 Aug 2027 – 13 Aug 2027** | Kigali | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **2 Aug 2027 – 13 Aug 2027** | Dubai | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **2 Aug 2027 – 13 Aug 2027** | Cape Town | Classroom / 10d | **$9,000 USD / KES 220,000** |
| **2 Aug 2027 – 13 Aug 2027** | Addis Ababa | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **2 Aug 2027 – 13 Aug 2027** | Singapore | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **2 Aug 2027 – 13 Aug 2027** | Istanbul | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **2 Aug 2027 – 13 Aug 2027** | Bangkok | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **2 Aug 2027 – 13 Aug 2027** | Accra | Classroom / 10d | **$8,000 USD / KES 220,000** |
| **16 Aug 2027 – 27 Aug 2027** | Nairobi | Classroom / 10d | **$3,000 USD / KES 220,000** |
| **16 Aug 2027 – 27 Aug 2027** | Kigali | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **16 Aug 2027 – 27 Aug 2027** | Dubai | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **16 Aug 2027 – 27 Aug 2027** | Cape Town | Classroom / 10d | **$9,000 USD / KES 220,000** |
| **16 Aug 2027 – 27 Aug 2027** | Addis Ababa | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **16 Aug 2027 – 27 Aug 2027** | Singapore | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **16 Aug 2027 – 27 Aug 2027** | Istanbul | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **16 Aug 2027 – 27 Aug 2027** | Bangkok | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **16 Aug 2027 – 27 Aug 2027** | Accra | Classroom / 10d | **$8,000 USD / KES 220,000** |
| **30 Aug 2027 – 10 Sep 2027** | Nairobi | Classroom / 10d | **$3,000 USD / KES 220,000** |
| **30 Aug 2027 – 10 Sep 2027** | Kigali | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **30 Aug 2027 – 10 Sep 2027** | Dubai | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **30 Aug 2027 – 10 Sep 2027** | Cape Town | Classroom / 10d | **$9,000 USD / KES 220,000** |
| **30 Aug 2027 – 10 Sep 2027** | Addis Ababa | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **30 Aug 2027 – 10 Sep 2027** | Singapore | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **30 Aug 2027 – 10 Sep 2027** | Istanbul | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **30 Aug 2027 – 10 Sep 2027** | Bangkok | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **30 Aug 2027 – 10 Sep 2027** | Accra | Classroom / 10d | **$8,000 USD / KES 220,000** |
| **13 Sep 2027 – 24 Sep 2027** | Nairobi | Classroom / 10d | **$3,000 USD / KES 220,000** |
| **13 Sep 2027 – 24 Sep 2027** | Kigali | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **13 Sep 2027 – 24 Sep 2027** | Dubai | Classroom / 10d | **$10,000 USD / KES 220,000** |

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| **13 Sep 2027 – 24 Sep 2027** | Cape Town | Classroom / 10d | **$9,000 USD / KES 220,000** |
| **13 Sep 2027 – 24 Sep 2027** | Addis Ababa | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **13 Sep 2027 – 24 Sep 2027** | Singapore | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **13 Sep 2027 – 24 Sep 2027** | Istanbul | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **13 Sep 2027 – 24 Sep 2027** | Bangkok | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **13 Sep 2027 – 24 Sep 2027** | Accra | Classroom / 10d | **$8,000 USD / KES 220,000** |
| **27 Sep 2027 – 8 Oct 2027** | Nairobi | Classroom / 10d | **$3,000 USD / KES 220,000** |
| **27 Sep 2027 – 8 Oct 2027** | Kigali | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **27 Sep 2027 – 8 Oct 2027** | Dubai | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **27 Sep 2027 – 8 Oct 2027** | Cape Town | Classroom / 10d | **$9,000 USD / KES 220,000** |
| **27 Sep 2027 – 8 Oct 2027** | Addis Ababa | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **27 Sep 2027 – 8 Oct 2027** | Singapore | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **27 Sep 2027 – 8 Oct 2027** | Istanbul | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **27 Sep 2027 – 8 Oct 2027** | Bangkok | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **27 Sep 2027 – 8 Oct 2027** | Accra | Classroom / 10d | **$8,000 USD / KES 220,000** |
| **11 Oct 2027 – 22 Oct 2027** | Nairobi | Classroom / 10d | **$3,000 USD / KES 220,000** |
| **11 Oct 2027 – 22 Oct 2027** | Kigali | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **11 Oct 2027 – 22 Oct 2027** | Dubai | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **11 Oct 2027 – 22 Oct 2027** | Cape Town | Classroom / 10d | **$9,000 USD / KES 220,000** |
| **11 Oct 2027 – 22 Oct 2027** | Addis Ababa | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **11 Oct 2027 – 22 Oct 2027** | Singapore | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **11 Oct 2027 – 22 Oct 2027** | Istanbul | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **11 Oct 2027 – 22 Oct 2027** | Bangkok | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **11 Oct 2027 – 22 Oct 2027** | Accra | Classroom / 10d | **$8,000 USD / KES 220,000** |
| **25 Oct 2027 – 5 Nov 2027** | Nairobi | Classroom / 10d | **$3,000 USD / KES 220,000** |
| **25 Oct 2027 – 5 Nov 2027** | Kigali | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **25 Oct 2027 – 5 Nov 2027** | Dubai | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **25 Oct 2027 – 5 Nov 2027** | Cape Town | Classroom / 10d | **$9,000 USD / KES 220,000** |
| **25 Oct 2027 – 5 Nov 2027** | Addis Ababa | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **25 Oct 2027 – 5 Nov 2027** | Singapore | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **25 Oct 2027 – 5 Nov 2027** | Istanbul | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **25 Oct 2027 – 5 Nov 2027** | Bangkok | Classroom / 10d | **$10,000 USD / KES 220,000** |

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| **25 Oct 2027 – 5 Nov 2027** | Accra | Classroom / 10d | **$8,000 USD / KES 220,000** |
| **8 Nov 2027 – 19 Nov 2027** | Nairobi | Classroom / 10d | **$3,000 USD / KES 220,000** |
| **8 Nov 2027 – 19 Nov 2027** | Kigali | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **8 Nov 2027 – 19 Nov 2027** | Dubai | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **8 Nov 2027 – 19 Nov 2027** | Cape Town | Classroom / 10d | **$9,000 USD / KES 220,000** |
| **8 Nov 2027 – 19 Nov 2027** | Addis Ababa | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **8 Nov 2027 – 19 Nov 2027** | Singapore | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **8 Nov 2027 – 19 Nov 2027** | Istanbul | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **8 Nov 2027 – 19 Nov 2027** | Bangkok | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **8 Nov 2027 – 19 Nov 2027** | Accra | Classroom / 10d | **$8,000 USD / KES 220,000** |
| **22 Nov 2027 – 3 Dec 2027** | Nairobi | Classroom / 10d | **$3,000 USD / KES 220,000** |
| **22 Nov 2027 – 3 Dec 2027** | Kigali | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **22 Nov 2027 – 3 Dec 2027** | Dubai | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **22 Nov 2027 – 3 Dec 2027** | Cape Town | Classroom / 10d | **$9,000 USD / KES 220,000** |
| **22 Nov 2027 – 3 Dec 2027** | Addis Ababa | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **22 Nov 2027 – 3 Dec 2027** | Singapore | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **22 Nov 2027 – 3 Dec 2027** | Istanbul | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **22 Nov 2027 – 3 Dec 2027** | Bangkok | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **22 Nov 2027 – 3 Dec 2027** | Accra | Classroom / 10d | **$8,000 USD / KES 220,000** |
| **6 Dec 2027 – 17 Dec 2027** | Nairobi | Classroom / 10d | **$3,000 USD / KES 220,000** |
| **6 Dec 2027 – 17 Dec 2027** | Kigali | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **6 Dec 2027 – 17 Dec 2027** | Dubai | Classroom / 10d | **$10,000 USD / KES 220,000** |
| **6 Dec 2027 – 17 Dec 2027** | Cape Town | Classroom / 10d | **$9,000 USD / KES 220,000** |
| **6 Dec 2027 – 17 Dec 2027** | Addis Ababa | Classroom / 10d | **$6,000 USD / KES 220,000** |
| **6 Dec 2027 – 17 Dec 2027** | Singapore | Classroom / 10d | **$10,000 USD / KES 220,000** |
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| **6 Dec 2027 – 17 Dec 2027** | Accra | Classroom / 10d | **$8,000 USD / KES 220,000** |

* Corporate discounts and customized cohort scheduling are available for teams of 3 or more participants.

# Course Curriculum & Modules

**Regulatory Strategy for Companion Diagnostics Training Course**

**Introduction**

**The convergence of diagnostics and therapeutics is rapidly transforming modern healthcare, ushering in the era of precision medicine and personalized treatment. At the heart of this revolution are companion diagnostics (CDx), in vitro diagnostic devices that provide critical information essential for the safe and effective use of a corresponding therapeutic product. The development and commercialization of these integrated drug-device products present a unique set of regulatory challenges, requiring a sophisticated understanding of global and regional frameworks like the FDA's Premarket Approval (PMA) pathway and the EU's In Vitro Diagnostic Regulation (IVDR). Regulatory Strategy for Companion Diagnostics Training Course is designed to equip professionals with the knowledge and strategic acumen needed to navigate this complex landscape, from initial biomarker discovery and co-development to market access and post-market surveillance.**

**Navigating the regulatory pathway for companion diagnostics is a strategic imperative for biopharmaceutical and diagnostic companies. It requires a deep understanding of evolving requirements, including clinical trial design, analytical and clinical validation, and the critical need for co-development planning to align drug and diagnostic timelines. This training will provide a comprehensive, practical guide to developing a robust regulatory strategy that minimizes risk, streamlines the approval process, and ensures that life-saving personalized therapies reach patients efficiently. Through expert-led sessions and hands-on case studies, participants will learn how to build effective cross-functional teams, manage complex submissions, and anticipate the future trends shaping the CDx market.**

**Course Duration**

**10 days**

## Course Objectives

Upon completion of this course, participants will be able to:

- Define companion diagnostics and explain their pivotal role in personalized medicine.
- Analyze the global regulatory landscape for CDx, including FDA, EMA, and other key international frameworks.
- Formulate an integrated regulatory strategy for the co-development of a drug and its associated CDx.
- Identify and address critical challenges in clinical trial design for CDx.
- Master the requirements for analytical and clinical validation of CDx assays.
- Develop a robust plan for regulatory submissions, including technical documentation and dossiers.
- Navigate the intricacies of the scientific consultation process with regulatory bodies.
- Implement strategies for post-market surveillance and lifecycle management of CDx.
- Evaluate the business models and collaborative partnerships between biopharma and diagnostic companies.
- Assess the impact of emerging technologies like Next-Generation Sequencing (NGS) and liquid biopsy on CDx regulation.
- Understand the unique considerations for CDx in immuno-oncology and other therapeutic areas.
- Mitigate risks associated with off-label use of diagnostics.
- Strategize for market access and reimbursement in a value-based healthcare system.

Target Audience

This course is designed for a diverse group of professionals involved in the development and commercialization of healthcare products, including:

- Regulatory Affairs Professionals: Seeking to specialize in the complexities of CDx.
- Clinical Research Scientists.
- R&D and Product Development Managers.
- Quality Assurance and Compliance Specialists.
- Market Access and Reimbursement Professionals.
- Biopharma Executives: Leading teams in the precision medicine space.
- Diagnostic Company Leaders: Driving strategic partnerships and product pipelines.
- Biomarker Scientists: Translating discoveries into regulatory-ready products.

Course Outline

## Module 1: Introduction to Precision Medicine and Companion Diagnostics

- Defining Precision Medicine.
- Role of Companion Diagnostics.
- Types of companion diagnostics
- Global market growth and key drivers.
- Ethical and Legal Considerations.
- Case studies: Importance of regulatory compliance

## Module 2: Regulatory Frameworks and Pathways

- FDA Regulatory Pathways: PMA vs. 510(k), and the De Novo classification.
- Understanding the new regulatory landscape for CDx.
- International Harmonization: ICH and other global initiatives.
- Early Regulatory Engagement: Pre-submission and scientific consultation.
- Global Regulatory Strategy: Navigating different country-specific requirements.
- Case studies: Navigating country-specific regulatory environments

## Module 3: Co-Development and Clinical Trial Design

- Integrated Development Plan.
- Biomarker Identification and Validation.
- Master protocols, umbrella, and basket trials.
- Powering studies for co-development.
- Managing the CTA (Clinical Trial Assay) vs. CDx pathway.
- Case studies: Key challenges in clinical trial design

## Module 4: Analytical and Clinical Validation

- Analytical Validation: Precision, accuracy, and reproducibility.
- Establishing clinical utility and performance.
- Linking clinical trial assays to the final CDx product.
- Ensuring specimen integrity and quality.
- Regulatory considerations for CDx software.
- Case Studies: Preparing a regulatory submission for CDx

## Module 5: Regulatory Submissions and Documentation

- Pre-Market Approval (PMA) Submission.
- Technical Documentation (EU.
- Labeling and Instructions for Use
- FDA eSTAR and eCopy submissions
- Responding to Regulatory Inquiries: Managing deficiencies and supplements
- Case studies: Key challenges in gaining market access

## Module 6: Post-Market Surveillance and Lifecycle Management

- Post-Market Surveillance (PMS.
- Adverse Event Reporting.
- Managing changes to an approved CDx.
- Periodic Safety Update Reports.
- CDx Lifecycle: From initial approval to next-generation assays.
- Case Studies: Risk management in post-market surveillance and approval.

## Module 7: Quality Management Systems (QMS) for CDx

- Overview of QMS in the CDx industry
- Key quality control standards
- Document control and traceability
- Implementing QMS in CDx development
- Case studies: Validation and verification processes

## Module 8: Business and Commercial Strategy

- Diagnostic company and biopharma collaboration.
- Market Access and Reimbursement.
- Value-based and competitive pricing.
- Market entry and launch strategies.
- Case Studies: Evaluating potential CDx opportunities.

### Module 9: Regulatory Strategy Planning

- Crafting a regulatory strategy for CDx
- Stakeholder collaboration in strategy development
- Key milestones in the regulatory lifecycle
- Managing timelines and budgets
- Case Study: Non-Small Cell Lung Cancer (NSCLC) and EGFR mutations.

### Module 10: Personalized Medicine and CDx

- Relationship between personalized medicine and companion diagnostics
- Regulatory requirements for personalized treatments
- Designing regulatory strategies for personalized therapies
- Integration of diagnostic and therapeutic strategies
- Case studies: Research in personalized medicine and CDx

### Module 11: Market Authorization and Reimbursement Pathways

- Understanding market authorization processes
- Reimbursement strategies for CDx
- Regulatory approval timelines
- Post-launch monitoring and reporting
- Case Study: Obtaining market authorization and secure public reimbursement

### Module 12: Clinical Data Management for Regulatory Approvals

- Best practices in clinical data management
- Data standards and regulatory compliance
- Statistical analysis for CDx validation
- Interpreting clinical data for regulatory approval
- Case studies on clinical data success

### Module 13: Ethical and Legal Considerations in Companion Diagnostics

- Ethical considerations in CDx development
- Legal aspects of patient consent and privacy
- Regulatory requirements for data protection
- Navigating ethical dilemmas in CDx approval
- Case studies in ethics and legal challenges

### Module 14: Final Project: Developing a CDx Regulatory Strategy

- Project Kick-off: Defining a new CDx product.
- Strategy Document: Drafting a comprehensive regulatory plan.
- Stakeholder Analysis: Mapping key internal and external players.
- Risk Assessment: Identifying potential regulatory hurdles.
- Final Presentation: Presenting the strategy to a panel.

### Module 15: Emerging Technologies and Trends

- Next-Generation Sequencing (NGS.
- Liquid Biopsy: The rise of non-invasive diagnostics.
- Regulatory frameworks for AI-driven CDx.
- Navigating PD-L1, TMB, and MSI.
- Expanding CDx into infectious diseases and CNS disorders.
- Case studies in regulatory success in emerging markets

Training Methodology

Our training methodology combines theoretical knowledge with practical application to ensure a comprehensive and engaging learning experience.

- Expert-Led Lectures.
- Interactive Workshops.

- In-Depth Case Studies.
- Role-Playing and Simulations.
- Peer-to-Peer Learning.
- Guest Speakers.
- Q&A Sessions: Direct interaction with instructors to address specific challenges.
- Practical Project

Register as a group from 3 participants for a Discount

Send us an email: info@datastatresearch.org or call +254724527104

Certification

Upon successful completion of this training, participants will be issued with a globally- recognized certificate.

Tailor-Made Course

We also offer tailor-made courses based on your needs.

Key Notes

a. The participant must be conversant with English.

b. Upon completion of training the participant will be issued with an Authorized Training Certificate

c. Course duration is flexible and the contents can be modified to fit any number of days.

d. The course fee includes facilitation training materials, 2 coffee breaks, buffet lunch and A Certificate upon successful completion of Training.

e. One-year post-training support Consultation and Coaching provided after the course.

f. Payment should be done at least a week before commence of the training, to DATASTAT CONSULTANCY LTD account, as indicated in the invoice so as to enable us prepare better for you.

## Certification & Learning Methodology

- Hands-on practical delivery with real-world datasets, case studies, and lab exercises.
- Post-training mentorship, access to class resources, and customized follow-up support.
- Participants who successfully complete the course receive an accredited Datastat Certificate of Completion.

## How to Enroll & Reserve Your Seat

1. Online Registration: Visit https://datastatresearch.org/courses/regulatory-strategy-for-companion-diagnostics-training-course to register online.
2. Email Booking: Send participant details to training@datastatresearch.org for official invoice & reservation.
3. Support & Assistance: Inquire via phone +254 724 527 104 | +254 734 969 612.