

Master of Clinical Research  
**REGULATORY AFFAIRS Specialization**  
**Sample Plans of Study**

**AUTUMN ENTRY – Full-time 12-Month Plan**

*Please note: 12-month plan of study is only available to students entering the program in autumn semester.*

| Year 1 – Autumn   |         | Year 1 – Spring   |         | Year 1 – Summer  |         |
|---|---------|---|---------|--|---------|
| Course  | credits | Course  | credits | Course   | credits |
| NURSING/PHR 7770: Fund. of Medical Product Development and Regulation (AU & SU) | 3       | NURSING 7781: Responsible Conduct of Research (SP)                              | 3       | PHR 5010: Fundamentals of Pharmacology [1] (SU)  | 3       |
| NURSING/PHR 7782: Clinical Research Design and Methods (AU)                     | 3       | NURSING/PHR 7405: Clinical Research Study and Site Management (SP, prerec 7770) | 3       | NURSING/PHR 7482: Prin. of Quality Management for Medical Product Dev. (SU, prerec 7405) | 3       |
| PHR 7784: Data Analysis and Interpretation in Clinical Research [2] (AU)        | 3       | PHR 7580: Principles of Safety Pharmacology (SP)                                | 3       | PHR 7460: Regulatory Strategy and Clinical Trial Reporting (SU, prerec 7770)             | 3       |
| PHR 7570: Pharmaceutical Safety and Risk Management (AU)                        | 3       | PHR 7572: Global Regulation of Medical Products (SP, prerec 7770)               | 3       | NURSING/PHR 7599: Culminating Project in Clinical Research (AU, SP, SU)                  | 3       |
|   |         |   |         |  |         |
|   |         |   |         |  |         |
|   | 12      |   | 12      |  | 12      |

- [1] Acceptable substitution: BIOPHRM 5600 – Introduction to General Pharmacology (AU, SP, SU)  
 The MCR degree requires a minimum of 36 credits. Students who have completed a general pharmacology course at any level (undergraduate or graduate, including OSU BSPPS graduates) or a graduate biostatistics course may substituted:  
     CBG/PHR 5700: Introduction to Personalized Therapeutics and Pharmacogenomics (3 credits, spring semester)  
     PHR 7572: Global Regulation of Medical Products (3 credits, spring semester)  
     PHR 7460: Regulatory Strategy and Clinical Trial Reporting (3 credits, summer term)  
     PHR 5005: Fundamentals of Pathophysiology (3 credits, summer term)
- [2] Acceptable substitution: PUBHBIO 6210 - Design and Analysis of Studies in the Health Sciences I (AU, SP, SU)

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**AUTUMN ENTRY – Part-time 24-Month Plan**

| Year 1 – Autumn   |         | Year 1 – Spring   |         | Year 1 – Summer  |         |
|---|---------|---|---------|--|---------|
| Course  | credits | Course  | credits | Course   | credits |
| NURSING/PHR 7770: Fund. of Medical Product Development and Regulation (AU & SU) | 3       | NURSING 7781: Responsible Conduct of Research (SP)                              | 3       | PHR 5010: Fundamentals of Pharmacology [1] (SU)  | 3       |
| NURSING/PHR 7782: Clinical Research Design and Methods (AU)                     | 3       | NURSING/PHR 7405: Clinical Research Study and Site Management (SP, prereq 7770) | 3       | NURSING/PHR 7482: Prin. of Quality Management for Medical Product Dev. (SU, prerec 7405) | 3       |
|   |         |   |         |  |         |
|   | 6       |   | 6       |  | 6       |
| Year 2 – Autumn   |         | Year 2 – Spring   |         | Year 2 – Summer  |         |
| Course  | credits | Course  | credits | Course   | credits |
| PHR 7784: Data Analysis and Interpretation in Clinical Research [2] (AU)        | 3       | PHR 7580: Principles of Safety Pharmacology (SP)                                | 3       | PHR 7460: Regulatory Strategy and Clinical Trial Reporting (SU, prerec 7770)             | 3       |
| PHR 7570: Pharmaceutical Safety and Risk Management (AU)                        | 3       | PHR 7572: Global Regulation of Medical Products (SP, prerec 7770)               | 3       | NURSING/PHR 7599: Culminating Project in Clinical Research (AU, SP, SU)                  | 3       |
|   |         |   |         |  |         |
|   | 6       |   | 6       |  | 6       |

- [1] Acceptable substitution: BIOPHRM 5600 – Introduction to General Pharmacology (AU, SP, SU)  
 The MCR degree requires a minimum of 36 credits. Students who have completed a general pharmacology course at any level (undergraduate or graduate, including OSU BSPPS graduates) or a graduate biostatistics course may substituted:  
 CBG/PHR 5700: Introduction to Personalized Therapeutics and Pharmacogenomics (3 credits, spring semester)  
 PHR 7572: Global Regulation of Medical Products (3 credits, spring semester)  
 PHR 7460: Regulatory Strategy and Clinical Trial Reporting (3 credits, summer term)  
 PHR 5005: Fundamentals of Pathophysiology (3 credits, summer term)
- [2] Acceptable substitution: PUBHBIO 6210 - Design and Analysis of Studies in the Health Sciences I (AU, SP, SU)

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**SPRING ENTRY – Part-time 24-Month Plan**

| Year 1 – Spring   |         | Year 1 – Summer  |         | Year 1 – Autumn  |         |
|---|---------|--|---------|--|---------|
| Course  | credits | Course   | credits | Course   | credits |
| NURSING 7781: Responsible Conduct of Research (SP)                              | 3       | NURSING/PHR 7770: Fund. of Medical Product Development and Regulation (AU & SU)          | 3       | NURSING/PHR 7782: Clinical Research Design and Methods (AU)              | 3       |
| PHR 7580: Principles of Safety Pharmacology (SP)                                | 3       | PHR 5010: Fundamentals of Pharmacology [1] (SU)  | 3       | PHR 7784: Data Analysis and Interpretation in Clinical Research [2] (AU) | 3       |
|   |         |  |         |  |         |
|   | 6       |  | 6       |  | 6       |
| Year 2 – Spring   |         | Year 2 – Summer  |         | Year 2 – Autumn  |         |
| Course  | credits | Course   | credits | Course   | credits |
| NURSING/PHR 7405: Clinical Research Study and Site Management (SP, prereq 7770) | 3       | NURSING/PHR 7482: Prin. of Quality Management for Medical Product Dev. (SU, prereq 7405) | 3       | PHR 7570: Pharmaceutical Safety and Risk Management (AU)                 | 3       |
| PHR 7572: Global Regulation of Medical Products (SP, prereq 7770)               | 3       | PHR 7460: Regulatory Strategy and Clinical Trial Reporting (SU, prereq 7770)             | 3       | NURSING/PHR 7599: Culminating Project in Clinical Research (AU, SP, SU)  | 3       |
|   |         |  |         |  |         |
|   | 6       |  | 6       |  | 6       |

- [1] Acceptable substitution: BIOPHRM 5600 – Introduction to General Pharmacology (AU, SP, SU)  
 The MCR degree requires a minimum of 36 credits. Students who have completed a general pharmacology course at any level (undergraduate or graduate, including OSU BSPPS graduates) or a graduate biostatistics course may substituted:  
 CBG/PHR 5700: Introduction to Personalized Therapeutics and Pharmacogenomics (3 credits, spring semester)  
 PHR 7572: Global Regulation of Medical Products (3 credits, spring semester)  
 PHR 7460: Regulatory Strategy and Clinical Trial Reporting (3 credits, summer term)  
 PHR 5005: Fundamentals of Pathophysiology (3 credits, summer term)
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**SUMMER ENTRY – Part-time 24-Month Plan**

| Year 1 – Summer  |         | Year 1 – Autumn  |         | Year 1 – Spring   |         |
|--|---------|--|---------|---|---------|
| Course   | credits | Course   | credits | Course  | credits |
| NURSING/PHR 7770: Fund. of Medical Product Development and Regulation (AU & SU)          | 3       | NURSING/PHR 7782: Clinical Research Design and Methods (AU)              | 3       | NURSING 7781: Responsible Conduct of Research (SP)                              | 3       |
| PHR 5010: Fundamentals of Pharmacology [1] (SU)  | 3       | PHR 7784: Data Analysis and Interpretation in Clinical Research [2] (AU) | 3       | NURSING/PHR 7405: Clinical Research Study and Site Management (SP, prereq 7770) | 3       |
|  |         |  |         |   |         |
|  | 6       |  | 6       |   | 6       |
| Year 2 – Summer  |         | Year 2 – Autumn  |         | Year 2 – Spring   |         |
| Course   | credits | Course   | credits | Course  | credits |
| NURSING/PHR 7482: Prin. of Quality Management for Medical Product Dev. (SU, prerec 7405) | 3       | PHR 7570: Pharmaceutical Safety and Risk Management (AU)                 | 3       | PHR 7572: Global Regulation of Medical Products (SP, prerec 7770)               | 3       |
| PHR 7460: Regulatory Strategy and Clinical Trial Reporting (SU, prerec 7770)             | 3       | NURSING/PHR 7599: Culminating Project in Clinical Research (AU, SP, SU)  | 3       | PHR 7580: Principles of Safety Pharmacology (SP)                                | 3       |
|  |         |  |         |   |         |
|  | 6       |  | 6       |   | 6       |

- [1] Acceptable substitution: BIOPHRM 5600 – Introduction to General Pharmacology (AU, SP, SU)  
 The MCR degree requires a minimum of 36 credits. Students who have completed a general pharmacology course at any level (undergraduate or graduate, including OSU BSPS graduates) or a graduate biostatistics course may substituted:  
 CBG/PHR 5700: Introduction to Personalized Therapeutics and Pharmacogenomics (3 credits, spring semester)  
 PHR 7572: Global Regulation of Medical Products (3 credits, spring semester)  
 PHR 7460: Regulatory Strategy and Clinical Trial Reporting (3 credits, summer term)  
 PHR 5005: Fundamentals of Pathophysiology (3 credits, summer term)
- [2] Acceptable substitution: PUBHBIO 6210 - Design and Analysis of Studies in the Health Sciences I (AU, SP, SU)